

Exhibit 47

*State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v.
Abbott Labs, Inc. et al., Civil Action No. 03-11226-PBS*

**Exhibit to the November 25, 2009 Declaration of Philip D. Robben
in Support of Defendants' Joint Motion for Partial Summary Judgment**

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

- - - - -
IN RE: PHARMACEUTICAL) MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE) CIVIL ACTION
PRICE LITIGATION) 01-CV-12257-PBS
THIS DOCUMENT RELATES TO)
U.S. ex rel. Ven-a-Care of) Judge Patti B. Saris
the Florida Keys, Inc.)
v.) Chief Magistrate
Abbott Laboratories, Inc.,) Judge Marianne B.
No. 06-CV-11337-PBS) Bowler
- - - - -

(cross captions appear on following pages)

Videotaped deposition of SUE GASTON

Volume I

Washington, D.C.

Thursday, January 24, 2008

9:00 a.m.

Henderson Legal Services, Inc.

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<p>1 UNITED STATES DISTRICT COURT 2 FOR THE DISTRICT OF MASSACHUSETTS 3 ----- 4 IN RE: PHARMACEUTICAL) MDL NO. 1456 5 INDUSTRY AVERAGE WHOLESALE) CIVIL ACTION 6 PRICE LITIGATION) 01-CV-12257-PBS 7) Judge Patti B. Saris 8 THIS DOCUMENT RELATES TO) Chief Magistrate 9 ALL CASES IN MDL NO. 1456) Judge Marianne B. 10 ----- Bowler 11 12 13 IN THE SUPERIOR COURT FOR THE STATE OF ALASKA 14 THIRD JUDICIAL DISTRICT AT ANCHORAGE 15 ----- 16 STATE OF ALASKA,) 17 Plaintiff,) 18 vs.) Case No. 19 ALPHARMA BRANDED PRODUCTS) 3AN-06-12026 CI 20 DIVISION, INC., et al.) 21 Defendants.) 22 -----</p>	<p>1 IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS 2 COUNTY DEPARTMENT, CHANCERY DIVISION 3 ----- 4 THE PEOPLE OF THE STATE OF) 5 ILLINOIS,) 6 Plaintiff,) Case No. 05 CH 02474 7 vs.) 8 ABBOTT LABORATORIES, et al.,) 9 Defendants.) 10 ----- 11 12 13 COMMONWEALTH OF KENTUCKY 14 FRANKLIN CIRCUIT COURT - DIV. I 15 ----- 16 COMMONWEALTH OF KENTUCKY, ex rel.) 17 GREGORY D. STUMBO, ATTORNEY GENERAL) 18 Plaintiff,) Civil Action 19 vs.) NO. 04-CI-1487 20 ALPHARMA USPD, INC., et al.,) 21 Defendants.) 22 -----</p>
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<p style="text-align: right;">Page 7</p> <p>1 UNITED STATES DISTRICT COURT 2 FOR THE DISTRICT OF MASSACHUSETTS 3 ----- 4 IN RE: PHARMACEUTICAL) MDL NO. 1456 5 INDUSTRY AVERAGE WHOLESALE) CIVIL ACTION 6 PRICE LITIGATION) 01-CV-12257-PBS 7 THIS DOCUMENT RELATES TO) 8 U.S. ex rel. Ven-a-Care of) Judge Patti B. Saris 9 the Florida Keys, Inc., et al) 10 v.) Chief Magistrate 11 Boehringer Ingelheim) Judge Marianne B. 12 Corporation, et al.,) Bowler 13 No. 07-CV-10248-PBS) 14 ----- 15 16 Videotaped deposition of SUE GASTON, held at 17 the law offices of Jones Day, 51 Louisiana Avenue, 18 N.W., Washington, D.C. 20001-2113, the proceedings 19 being recorded stenographically by Jonathan Wonnell, 20 a Registered Professional Court Reporter and Notary 21 Public of the District of Columbia, and transcribed 22 under his direction.</p>	<p style="text-align: right;">Page 9</p> <p>1 APPEARANCES (Cont'd) 2 3 On behalf of the State of Alabama: 4 5 SCARLETTE M. TULEY, ESQ. (via phone) 6 Beasley, Allen, Crow, Methvin, Portis & 7 Miles, P.C. 8 218 Commerce Street 9 Montgomery, Alabama 36104 10 (800) 898-2034 11 scarlette.tuley@beasleyallen.com 12 13 On behalf of the State of Florida: 14 15 MARY S. MILLER, ESQ. (via phone) 16 Office of the Attorney General of Florida 17 PL-01, The Capitol 18 Tallahassee, Florida 32399-1050 19 (850) 414-3600 20 mary_miller@oag.state.fl.us 21 22 (Cont'd)</p>

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<p>1 A P P E A R A N C E S (Cont'd)</p> <p>2</p> <p>3 On behalf of the City of New York and all New</p> <p>4 York Counties other than Nassau and</p> <p>5 Orange; the States of Wisconsin,</p> <p>6 Illinois, Kentucky, Idaho, Alaska and</p> <p>7 Hawaii:</p> <p>8</p> <p>9 MICHAEL WINGET-HERNANDEZ, ESQ.</p> <p>10 Winget-Hernandez, LLC</p> <p>11 3112 Windsor Road, Suite 228</p> <p>12 Austin, Texas 78703</p> <p>13 michael@winget-hernandez.com</p> <p>14</p> <p>15 On behalf of Ven-A-Care of the Florida Keys, Inc.:</p> <p>16</p> <p>17 MARJORY P. ALBEE, ESQ.</p> <p>18 Mager & Goldstein LLP</p> <p>19 1818 Market Street, Suite 3710</p> <p>20 Philadelphia, Pennsylvania 19103</p> <p>21 (215) 640-3280</p> <p>22 malbee@magergoldstein.com</p>	<p>1 A P P E A R A N C E S (Cont'd)</p> <p>2</p> <p>3 On behalf of Bristol-Myers Squibb:</p> <p>4</p> <p>5 DIANNE M. PETERSON, ESQ. (via phone)</p> <p>6 Hogan & Hartson</p> <p>7 875 Third Avenue</p> <p>8 New York, New York 10022</p> <p>9 (212) 918-3000</p> <p>10 dmpeterson@hhlaw.com</p> <p>11</p> <p>12 On behalf of Dey, Inc., Dey, L.P. and Mylan:</p> <p>13</p> <p>14 SARAH L. REID, ESQ.</p> <p>15 Kelley, Drye & Warren LLP</p> <p>16 101 Park Avenue</p> <p>17 New York, New York 10178</p> <p>18 (212) 808-7720</p> <p>19 sreid@kelleydrye.com</p> <p>20</p> <p>21</p> <p>22 (Cont'd)</p>
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<p>1 A P P E A R A N C E S (Cont'd)</p> <p>2 On behalf of Abbott Laboratories, Inc.:</p> <p>3</p> <p>4 DAVID TORBORG, ESQ.</p> <p>5 SEAN P. MALONE, ESQ.</p> <p>6 Jones Day</p> <p>7 51 Louisiana Avenue, N.W.</p> <p>8 Washington, D.C. 20001-2113</p> <p>9 (202) 879-3939</p> <p>10 dstorborg@jonesday.com</p> <p>11 spmalone@jonesday.com</p> <p>12</p> <p>13 On behalf of Aventis Pharmaceuticals and</p> <p>14 Sanofi Synthelabo:</p> <p>15</p> <p>16 JENNIFER H. MCGEE, ESQ.</p> <p>17 Shook, Hardy & Bacon, LLP</p> <p>18 600 Fourteenth Street, N.W.</p> <p>19 Suite 800</p> <p>20 Washington, D.C. 20005-2004</p> <p>21 (202) 783-8400</p> <p>22 jmcgee@shb.com</p>	<p>1 A P P E A R A N C E S (Cont'd)</p> <p>2</p> <p>3 On behalf of Roxane Laboratories and</p> <p>4 Boehringer Ingelheim:</p> <p>5</p> <p>6 ERIC GORTNER, ESQ.</p> <p>7 Kirkland & Ellis</p> <p>8 200 East Randolph Drive</p> <p>9 Chicago, Illinois 60601</p> <p>10 (312) 861-2285</p> <p>11 egortner@kirkland.com</p> <p>12</p> <p>13 On behalf of Sandoz, Inc.:</p> <p>14</p> <p>15 DAVID L. KLEINMAN, ESQ. (via phone)</p> <p>16 White & Case LLP</p> <p>17 1155 Avenue of the Americas</p> <p>18 New York, New York 10036-2787</p> <p>19 (212) 819-2567</p> <p>20 dkleinman@whitecase.com</p> <p>21</p> <p>22</p>

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<p style="text-align: right;">Page 18</p> <p>1 PROCEEDINGS 2 (9:35 a.m.) 3 THE VIDEOGRAPHER: In the United States 4 District Court for the District of Massachusetts, In 5 Re: Pharmaceutical Industry Average Wholesale Price 6 Litigation, related to U.S. ex rel. Ven-A-Care of 7 the Florida Keys, Incorporated versus Abbott 8 Laboratories Incorporated et al., Case Number 01 CV 9 12257 PBS, and other cases cross noticed. This is 10 the deposition of Sue Gaston. 11 Today's date is January 24th 2008. The 12 location of the deposition is Jones Day, 51 13 Louisiana Avenue, Northwest, Washington, D.C. Will 14 counsel please identify yourselves and state whom 15 you represent? 16 MR. TORBORG: David Torborg from Jones 17 Day representing Abbott Laboratories. 18 MR. GORTNER: Good morning. Eric Gortner 19 from Kirkland & Ellis representing Roxane 20 Laboratories, Inc. and entities affiliated with 21 Boehringer Ingelheim Corporation. 22 MR. RORTVEDT: Victor Rortvedt, Endo</p>	<p style="text-align: right;">Page 20</p> <p>1 MS. STAFFORD: Leslie Stafford on behalf 2 of the Centers for Medicare and Medicaid Services. 3 MS. MARTINEZ: Ani Martinez on behalf of 4 the United States. And I'd just like to ask, David, 5 at a particular point I'd like to make a comment 6 before you begin regarding cross notices. 7 MR. TORBORG: Perhaps it makes sense to 8 have the people on the phone identify themselves 9 before we go into the preliminary matters. 10 Would those on the phone please state 11 your name and who you represent? 12 MS. MILLER: Yes, this is Mary Miller for 13 the attorney general on behalf of the State of 14 Florida on the cross noticed matter filed by Mylan. 15 MS. APPLEBERRY: Ginger Appleberry from 16 Locke, Lord, Bissell & Liddell representing 17 Schering, Schering-Plough and Warrick 18 Pharmaceuticals. 19 MS. MILLER: Joining Mary Miller for the 20 State of Florida is Kirk Rogers. 21 MS. TULEY: This is Scarlett Tuley from 22 the law firm of Beasley Allen for the state of</p>
<p style="text-align: right;">Page 19</p> <p>1 Pharmaceuticals. 2 MS. REID: Sarah Reid from Kelley, Drye & 3 Warren representing Dey and on the cross-noticed 4 deposition also representing Mylan Laboratories. 5 MS. MCGEE: Jennifer McGee from Shook, 6 Hardy & Bacon representing Aventis Pharmaceuticals 7 and Sanofi Synthelabo. 8 MR. BUEKER: John Bueker from Ropes & 9 Gray on behalf of Schering-Plough Corporation, 10 Schering Corporation and Warrick Pharmaceuticals 11 Corporation. 12 MS. VONDRICH: Clara Vondrich on behalf 13 of Ethex Corporation. 14 MR. WINGET-HERNANDEZ: Michael Winget- 15 Hernandez. I'm here on behalf of the City of New 16 York and the New York Counties in the MDL 1456 17 except for Orange and Nassau. Also on behalf of the 18 states of Wisconsin, Illinois, Kentucky, Alaska, 19 Idaho and Hawaii. 20 MS. ALBEE: Marjory Albee from the law 21 firm of Mager & Goldstein on behalf of Ven-A-Care of 22 the Florida Keys, Inc.</p>	<p style="text-align: right;">Page 21</p> <p>1 Alabama. 2 MR. KLEINMAN: This is David Kleinman 3 from White & Case for Sandoz, Inc. 4 MS. PETERSON: Diane Peterson from the 5 firm of Hogan & Hartson on behalf of Bristol-Myers 6 Squibb. 7 THE VIDEOGRAPHER: Is there anyone else 8 on the phone? Okay. 9 The court reporter is Jon Wonnell. The 10 video camera operator is Conway Barker, both on 11 behalf of Henderson Legal Services. This deposition 12 commences at 9:37. Please swear in the witness. 13 * * * * * 14 Whereupon, 15 SUE GASTON, 16 called as a Witness, was duly sworn by 17 Jonathan Wonnell, a Notary Public in and 18 for the District of Columbia, and was 19 examined and testified as follows. 20 * * * * * 21 THE VIDEOGRAPHER: Your may proceed. 22 MR. TORBORG: Ani, you had some</p>

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<p>1 preliminary comments?</p> <p>2 MS. MARTINEZ: Yes. This is Ani</p> <p>3 Martinez. My comment is with respect to any state</p> <p>4 cross notices of this deposition. And it's just to</p> <p>5 say that the United States is agreeable to you all</p> <p>6 cross noticing this and being here. However, only</p> <p>7 subject to the way that it was contemplated by the</p> <p>8 MDL judge, Judge Saris. And what she contemplated</p> <p>9 is that if you all participate in these depositions</p> <p>10 any issues that may arise regarding it would be</p> <p>11 resolved by her.</p> <p>12 And so I just wanted to say that the</p> <p>13 United States is in no way offering Ms. Gaston as a</p> <p>14 witness in response to those notices in any way that</p> <p>15 would lead to the United States having to go to</p> <p>16 state court on any issue or having state</p> <p>17 jurisdiction over this particular deposition.</p> <p>18 That's all.</p> <p>19 EXAMINATION BY COUNSEL FOR THE ABBOTT LABORATORIES</p> <p>20 BY MR. TORBORG:</p> <p>21 Q. Good morning, Ms. Gaston.</p> <p>22 A. Good morning.</p>	<p>1 Q. Do you have any plans to take a different</p> <p>2 job?</p> <p>3 A. No.</p> <p>4 Q. Have you ever been deposed before?</p> <p>5 A. Yes.</p> <p>6 Q. How many times have you been deposed?</p> <p>7 A. Once.</p> <p>8 Q. Can you give me just a general background</p> <p>9 or what the nature of the deposition was and the</p> <p>10 case? I'm sorry. The nature of the case.</p> <p>11 A. It was -- from my recollection it was the</p> <p>12 Federal Trade Commission and Mylan Labs.</p> <p>13 Q. Do you recall what the nature of that</p> <p>14 litigation was?</p> <p>15 A. Yes. It was my understanding that the</p> <p>16 Federal Trade Commission was looking into Mylan Labs</p> <p>17 because they -- there was an indication that they</p> <p>18 have purchased some of the bulk material for some of</p> <p>19 their generic drugs so the other competitor</p> <p>20 companies that also made that same product, they</p> <p>21 were unable to obtain the bulk materials in order to</p> <p>22 make the competitive product. So sort of cornering</p>
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<p>1 Q. Could you please state your full name for</p> <p>2 the record?</p> <p>3 A. It's see Susan E. Gaston.</p> <p>4 Q. Thank you. My name is David Torborg and</p> <p>5 I'm an attorney from the law firm of Jones Day. And</p> <p>6 we represent Abbott Laboratories in this case. And</p> <p>7 we've never spoken before today; is that right?</p> <p>8 A. Correct.</p> <p>9 Q. What is your current address?</p> <p>10 A. Home address?</p> <p>11 Q. Yes, please.</p> <p>12 A. 9011 Thugmorton Road, Baltimore,</p> <p>13 Maryland, 21234.</p> <p>14 Q. And what is your current business</p> <p>15 address?</p> <p>16 A. 7500 Security Boulevard.</p> <p>17 Q. And is that the offices of CMS?</p> <p>18 A. The Center for Medicare and Medicaid</p> <p>19 Services.</p> <p>20 Q. Thank you. Do you have any plans to move</p> <p>21 your personal residence in the near future?</p> <p>22 A. No.</p>	<p>1 the market kind of --</p> <p>2 Q. Antitrust type matter?</p> <p>3 A. Correct.</p> <p>4 Q. Have you ever testified at a trial or</p> <p>5 hearing?</p> <p>6 A. Yes.</p> <p>7 Q. Can you tell me about that?</p> <p>8 A. It was testifying to the grand jury in</p> <p>9 Boston.</p> <p>10 Q. And when was that?</p> <p>11 A. When?</p> <p>12 Q. Yes.</p> <p>13 A. I can't recall.</p> <p>14 Q. Was it within the last two years?</p> <p>15 A. It was prior to that.</p> <p>16 Q. What's your best guess of when it was? I</p> <p>17 don't need an exact date, but your best guess at</p> <p>18 when it was?</p> <p>19 A. Early 2000. Maybe the end of 1999. I'm</p> <p>20 really not sure.</p> <p>21 Q. And did that relate in any way to</p> <p>22 prescription drugs?</p>

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<p style="text-align: right;">Page 26</p> <p>1 A. Yes.</p> <p>2 Q. How did you come to testify before the</p> <p>3 grand jury in Boston in early 2000 relating to</p> <p>4 prescription drugs?</p> <p>5 A. Did you want to know what the issue was?</p> <p>6 Q. Yes.</p> <p>7 A. It was concerning repackagers,</p> <p>8 manufacturers that were considered repackagers.</p> <p>9 Q. And what is a repackager?</p> <p>10 A. A repackager is a company that repackages</p> <p>11 a drug under their own NDC number.</p> <p>12 Q. Do you recall which manufacturers were</p> <p>13 involved?</p> <p>14 A. No, I don't.</p> <p>15 Q. Do you recall any of the ones that were</p> <p>16 involved?</p> <p>17 A. I know Kaiser was an issue.</p> <p>18 Q. And how long did you testify before the</p> <p>19 grand jury?</p> <p>20 A. I appeared twice.</p> <p>21 Q. For how long were you on the stand?</p> <p>22 A. I don't remember.</p>	<p style="text-align: right;">Page 28</p> <p>1 Q. Do you have any general recollection at</p> <p>2 all about whether those types of meetings took</p> <p>3 place?</p> <p>4 A. They could have occurred.</p> <p>5 Q. And why do you see that they could have</p> <p>6 occurred? Do you have a general recollection about</p> <p>7 that or --</p> <p>8 A. No. Just the nature of the program.</p> <p>9 Q. Okay. Before we get too far along I'd</p> <p>10 like to go over some guidelines about how I'd like</p> <p>11 to proceed today. First -- and you've done a great</p> <p>12 job of this so far -- you'll need to respond</p> <p>13 verbally to my questions so the court reporter can</p> <p>14 pick it up. And the most important guideline is</p> <p>15 this. Please tell me if you don't understand any</p> <p>16 question that I ask. Otherwise I'll assume that you</p> <p>17 understand the question and are able to provide a</p> <p>18 response.</p> <p>19 If it helps us get on the same</p> <p>20 wavelength, feel free to ask me a question. You've</p> <p>21 already done that once today. That's fine. I'm</p> <p>22 just trying to get your -- I just want us to be on</p>
<p style="text-align: right;">Page 27</p> <p>1 Q. Did this testimony have anything to do</p> <p>2 with issues regarding average wholesale price?</p> <p>3 A. No, not that I'm aware of.</p> <p>4 Q. Did it have anything to do with the</p> <p>5 pricing of drugs?</p> <p>6 A. Not that I'm aware of.</p> <p>7 Q. Have you given any other testimony</p> <p>8 besides what you told me already?</p> <p>9 A. No.</p> <p>10 Q. Have you ever testified before</p> <p>11 Congress --</p> <p>12 A. No.</p> <p>13 Q. -- or any congressional committee?</p> <p>14 A. No.</p> <p>15 Q. Have you ever met with any congressional</p> <p>16 committees?</p> <p>17 A. Not that I remember.</p> <p>18 Q. Were you aware of any others in your</p> <p>19 office meeting with congressional committees</p> <p>20 regarding issues on drug pricing?</p> <p>21 A. I can't specifically remember if they</p> <p>22 did.</p>	<p style="text-align: right;">Page 29</p> <p>1 the same wavelength so you understand what I'm</p> <p>2 asking. Okay?</p> <p>3 A. Okay.</p> <p>4 Q. From time to time Ms. Martinez may say</p> <p>5 objection after I ask a question. The objections</p> <p>6 are being made for purposes of the record. Unless</p> <p>7 Ms. Martinez specifically tells you not to answer my</p> <p>8 question you are to answer my question. Okay?</p> <p>9 A. Okay.</p> <p>10 Q. And we've had an agreement with counsel</p> <p>11 in previous depositions that one objection for that</p> <p>12 side of the table will suffice for all cases so we</p> <p>13 don't have a chorus of objections. Is that</p> <p>14 agreement acceptable to everyone here today?</p> <p>15 MR. WINGET-HERNANDEZ: Actually, I think</p> <p>16 the agreement applies so both sides of the table.</p> <p>17 MR. TORBORG: That's fine.</p> <p>18 MS. ALBEE: Is there also an agreement</p> <p>19 that objection form suffices as an objection to the</p> <p>20 form without further articulation?</p> <p>21 MR. TORBORG: Yes. That would be</p> <p>22 preferred under the rules.</p>

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<p style="text-align: right;">Page 30</p> <p>1 MS. MARTINEZ: I just want to state for 2 the record I think it's possible that there's some 3 people on this side that are not sort of plaintiff. 4 So I just wanted to -- I think there's two at the 5 end that are representing defendants. So we'll just 6 say that objections either by Mr. Winget, Ms. Albee 7 or myself -- I don't expect Ms. Stafford -- Ms. 8 Stafford will probably rely on me to make the 9 objections -- will count for the plaintiff's side, 10 shall we said. 11 MR. TORBORG: But I thought Ms. Hernandez 12 says it doesn't matter. 13 MS. MARTINEZ: Excuse me? 14 MR. TORBORG: I think Mr. Hernandez said 15 it doesn't matter if you're plaintiff or defendant. 16 MR. WINGET-HERNANDEZ: I hate that we're 17 having to go down this rabbit trail, but my 18 understanding of the agreement is that if one of the 19 defendants' counsel raises an objection that 20 objection is good for all of defense counsel. The 21 same is true on the plaintiff's side. If one of 22 plaintiff's counsel raises an objection then the</p>	<p style="text-align: right;">Page 32</p> <p>1 do that. She has copies as well. We're trying to 2 save some trees here, but of course not all trees. 3 MR. WINGET-HERNANDEZ: You should be 4 struck by lightning for saying that. 5 BY MR. TORBORG: 6 Q. Finally, I will try to take a break about 7 every hour or what otherwise makes sense. Let me 8 know if you need to take a break at any time. 9 A. Okay. 10 Q. Do you have any questions before we get 11 started? 12 A. No. 13 Q. First I'd like to walk through your 14 professional career starting with college. And did 15 you attend college? 16 A. No. 17 Q. Have you taken any post high school 18 educational courses? 19 A. Yes. 20 Q. Can you tell me about those? 21 A. Specifically, no. I'm not -- I can't 22 remember. I know there was an English course. But</p>
<p style="text-align: right;">Page 31</p> <p>1 objection is good for all the plaintiffs' counsel. 2 That's my understanding of it. Do you agree? 3 MR. TORBORG: I agree for Abbott Labs. 4 That's all I can agree for. If anyone has an 5 objection, please raise it. 6 BY MR. TORBORG: 7 Q. Ms. Gaston, you may have wondered what's 8 next to you and Ms. Martinez. There's a couple 9 boxes of binders that have orange covers. What 10 those are are copies of documents that have been 11 marked as exhibits in previous depositions that have 12 come before you. 13 I will ask you -- fortunately I will not 14 be asking you questions about all of those, but I 15 will be asking you questions about some of them. 16 And I will tell you the exhibit number. And on the 17 front of each binder is a sticker that will tell you 18 which exhibits are in that binder. It will be say 19 Abbott Exhibit 25 through whatever, 50, and I'm 20 going to ask you to pull that out when I get those. 21 But that's what those are and Ms. 22 Martinez has been kind enough in the past to help us</p>	<p style="text-align: right;">Page 33</p> <p>1 other than that, unless they were job-related 2 courses, which I really can't remember exactly which 3 courses I took. Are you talking specifically 4 college or are you talking -- 5 Q. Any educational courses after high 6 school. That's what I'm asking about. And what you 7 recall is taking some English-related courses? 8 (Telephone objection.) 9 MR. TORBORG: Excuse me a second. 10 There's something odd going on on the phone. 11 MR. WINGET-HERNANDEZ: We're going to go 12 off the record and see if we can't fix this. 13 THE VIDEOGRAPHER: Off the record at 14 9:49. 15 (Recess.) 16 THE VIDEOGRAPHER: On the record at 9:15. 17 BY MR. TORBORG: 18 Q. I'm sorry about that, Ms. Gaston. Where 19 was I? We were talking about courses you've taken 20 after high school. And you indicated that you've 21 taken some English-related courses; is that right? 22 A. Yes, but I can't remember any other</p>

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<p>1 specific courses.</p> <p>2 Q. And where did you take those courses?</p> <p>3 A. The location was at Social Security. But</p> <p>4 it was through one of the local colleges.</p> <p>5 Q. Have you taken any educational courses in</p> <p>6 the area of pharmacy?</p> <p>7 A. No.</p> <p>8 Q. Have you taken any educational courses</p> <p>9 relating to health care in general?</p> <p>10 A. Not that I can remember.</p> <p>11 Q. Have you ever worked at a pharmacy?</p> <p>12 A. No.</p> <p>13 Q. Is it fair to say that what you know</p> <p>14 about the world of pharmacy is what you've learned</p> <p>15 on the job at HCFA?</p> <p>16 A. Correct.</p> <p>17 Q. What was your -- did you graduate from</p> <p>18 high school?</p> <p>19 A. Yes.</p> <p>20 Q. What was your first job after graduating</p> <p>21 from high school?</p> <p>22 A. I worked for a moving and storage</p>	<p>1 A. The paper that Ani gave you, on the top</p> <p>2 it says EOD date.</p> <p>3 Q. Yes.</p> <p>4 A. What does that say?</p> <p>5 Q. 1/30/1974?</p> <p>6 A. Okay. I want to correct myself. It's</p> <p>7 '74, not '79.</p> <p>8 Q. That's when you started with Social</p> <p>9 Security in the typing pool?</p> <p>10 A. Yes.</p> <p>11 Q. Thank you. So you worked in the moving</p> <p>12 company until 1974; is that right?</p> <p>13 A. Correct.</p> <p>14 Q. And how long did you work in the typing</p> <p>15 pool at the Social Security Administration?</p> <p>16 A. I really don't know how long that was.</p> <p>17 Q. Ten years, more than ten years?</p> <p>18 A. No. It wasn't that long.</p> <p>19 Q. What was your next job?</p> <p>20 A. I worked for Office of the General</p> <p>21 Counsel. It was a clerical job.</p> <p>22 Q. Was that within the Social Security</p>
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<p>1 company.</p> <p>2 Q. What year did you graduate from high</p> <p>3 school?</p> <p>4 A. '73.</p> <p>5 Q. And how long did you work for the moving</p> <p>6 company?</p> <p>7 A. Until '79.</p> <p>8 Q. And then what did you do after that?</p> <p>9 What was your next job?</p> <p>10 A. I started with the Social Security</p> <p>11 Administration.</p> <p>12 Q. When did you start with the Social</p> <p>13 Security Administration?</p> <p>14 A. In a typing pool.</p> <p>15 Q. Excuse me?</p> <p>16 A. A typing pool.</p> <p>17 Q. A typing pool. And when did you start</p> <p>18 that job?</p> <p>19 A. In '79.</p> <p>20 Q. How long did you serve in that job?</p> <p>21 A. Can I ask you a question?</p> <p>22 Q. Sure.</p>	<p>1 Administration?</p> <p>2 A. Correct.</p> <p>3 Q. Who did you work with? Who was your</p> <p>4 boss?</p> <p>5 A. I don't recall.</p> <p>6 Q. How long did you work in that position?</p> <p>7 A. I don't recall.</p> <p>8 Q. More than ten years?</p> <p>9 A. No. Less.</p> <p>10 Q. After that what was your next job?</p> <p>11 A. I worked for Office of the Actuary.</p> <p>12 Q. And was that still within the SSA?</p> <p>13 A. Correct.</p> <p>14 Q. What did you do in that job?</p> <p>15 A. Clerical.</p> <p>16 Q. Do you know how long you had that job?</p> <p>17 A. No, I don't.</p> <p>18 Q. What was your next job after that?</p> <p>19 A. Division of classification.</p> <p>20 Q. That's still within the SSA?</p> <p>21 A. Correct.</p> <p>22 Q. What was the nature of your job in that</p>

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<p style="text-align: right;">Page 38</p> <p>1 division?</p> <p>2 A. Clerical.</p> <p>3 Q. After that what did you do?</p> <p>4 A. Disability operations in Social Security.</p> <p>5 Q. What was the nature of your job in that?</p> <p>6 A. Processing foreign claims. Social</p> <p>7 Security claims.</p> <p>8 Q. Was that a clerical or a --</p> <p>9 A. I was a benefit authorizer.</p> <p>10 Q. Okay. So that's more than clerical?</p> <p>11 A. Correct.</p> <p>12 Q. So you were to look at the forms and</p> <p>13 decide whether or not to -- or make recommendations</p> <p>14 on whether or not to authorize benefits?</p> <p>15 A. No. We just -- we did more of -- we</p> <p>16 didn't determine or authorize claims. But we</p> <p>17 processed the claims after the authorization</p> <p>18 occurred.</p> <p>19 Q. What was the next job you had after that?</p> <p>20 A. With HCFA.</p> <p>21 Q. Okay. Was this your first job with HCFA?</p> <p>22 A. Yes.</p>	<p style="text-align: right;">Page 40</p> <p>1 Q. From 1991 to February of 2003 you were</p> <p>2 health insurance specialist at HCFA; is that right?</p> <p>3 A. Yes. Our actual title when I first</p> <p>4 started was different than health insurance</p> <p>5 specialist. But it was all basically the same job.</p> <p>6 They changed the name of the job.</p> <p>7 Q. But your duties and responsibility in</p> <p>8 this job were the same from April of 1991 through</p> <p>9 February of '03; is that right?</p> <p>10 A. Correct.</p> <p>11 Q. And tell me about your job at that time.</p> <p>12 What were you doing?</p> <p>13 A. I was working with the Medicaid drug</p> <p>14 rebate program pharmacy reimbursement and coverage</p> <p>15 issues.</p> <p>16 Q. When you say pharmacy reimbursement, what</p> <p>17 do you mean by that?</p> <p>18 A. It's drug reimbursement with the -- we</p> <p>19 did state plan amendments and covered issues that</p> <p>20 came up for drug coverage under Medicaid.</p> <p>21 Q. And when you say drug coverage under</p> <p>22 Medicaid, you mean what drugs would be covered under</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. And what was your position there?</p> <p>2 A. I don't recall the job title at that</p> <p>3 time.</p> <p>4 Q. On the resume that you created for</p> <p>5 purposes of this deposition -- I appreciate that --</p> <p>6 the last one I have on the page runs the dates May</p> <p>7 1988 to April 1991, post entitlement technical</p> <p>8 expert, Social Security Administration, Office of</p> <p>9 Disability and International Operations. Have we</p> <p>10 talked about that one yet?</p> <p>11 A. Well, I went in there as a benefit</p> <p>12 authorizer and then I was promoted to the post</p> <p>13 entitlement technical expert. But it was still</p> <p>14 foreign claims and it was -- from benefit authorizer</p> <p>15 to the post entitlement job, it was all within those</p> <p>16 years.</p> <p>17 Q. And you worked at the Social Security</p> <p>18 Administration until April of 1991; is that right?</p> <p>19 A. Correct.</p> <p>20 Q. During your time at the SSA did you</p> <p>21 confront issues relating to pharmacy?</p> <p>22 A. No.</p>	<p style="text-align: right;">Page 41</p> <p>1 Medicaid, correct?</p> <p>2 A. Right.</p> <p>3 Q. Not necessarily, in that category at</p> <p>4 least, the level of payment to be paid; is that</p> <p>5 right?</p> <p>6 A. Both. Whether a drug was covered under</p> <p>7 Medicaid and also any of the payment issues that</p> <p>8 would come up, what states would pay by the state</p> <p>9 planned amendments.</p> <p>10 Q. You also referenced the Medicaid drug</p> <p>11 rebate program; is that right?</p> <p>12 A. Correct.</p> <p>13 Q. What was the nature of your involvement</p> <p>14 in that during this time?</p> <p>15 A. The Medicaid drug rebate program</p> <p>16 determines if drugs are covered under Medicaid.</p> <p>17 Q. What was the nature of your job with</p> <p>18 respect to the Medicaid drug rebate program? What</p> <p>19 did you do?</p> <p>20 A. Overseeing the policy.</p> <p>21 Q. When you say overseeing policy, what do</p> <p>22 you mean by that?</p>

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<p>1 A. Working on any policy-related issues</p> <p>2 concerning the Medicaid drug rebate program.</p> <p>3 Q. With respect to state plan amendments and</p> <p>4 drug reimbursement, what was the nature of your work</p> <p>5 in that area?</p> <p>6 A. Working with the regional office and</p> <p>7 reviewing the state plan amendments that are</p> <p>8 submitted by the states.</p> <p>9 Q. We'll talk about that a little bit more</p> <p>10 today. Who was your boss during this time from</p> <p>11 April 1991 through February of 2003?</p> <p>12 A. Larry Reed.</p> <p>13 Q. What was Mr. Reed's title? Do you know?</p> <p>14 A. In the beginning he was a branch chief.</p> <p>15 At times he was a technical director. Other times</p> <p>16 he was a director.</p> <p>17 Q. Was there anyone sort of in the chain of</p> <p>18 command between Mr. Reed and yourself or did you</p> <p>19 report directly to Mr. Reed?</p> <p>20 A. I don't quite understand your question.</p> <p>21 Q. Have you seen an organizational chart</p> <p>22 before that has little boxes and lines?</p>	<p>1 Q. And CMSO is the predecessor name for the</p> <p>2 Medicaid Bureau; is that right?</p> <p>3 A. Correct.</p> <p>4 MS. MARTINEZ: Objection, form. I think</p> <p>5 you said it backwards.</p> <p>6 MR. TORBORG: Yes. Successor name.</p> <p>7 You're right.</p> <p>8 MS. MARTINEZ: Okay.</p> <p>9 BY MR. TORBORG:</p> <p>10 Q. Just so we're clear, CMSO is the</p> <p>11 successor name to the Medicaid Bureau?</p> <p>12 A. Right.</p> <p>13 Q. And in February of 2003 you switched</p> <p>14 jobs; is that right?</p> <p>15 A. Correct.</p> <p>16 Q. And that's your current job, right?</p> <p>17 A. Yes.</p> <p>18 Q. And what is the nature of your job there?</p> <p>19 A. I'm the team lead for dispute resolution</p> <p>20 of the Medicaid drug rebate program.</p> <p>21 Q. Do you work on state plan amendments</p> <p>22 anymore?</p>
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<p>1 A. Yes.</p> <p>2 Q. Would there be a box between you and Mr.</p> <p>3 Reed?</p> <p>4 A. A box between us? No.</p> <p>5 Q. Or did you report directly to Mr. Reed?</p> <p>6 A. To Larry Reed.</p> <p>7 Q. Okay. Who else did you work with --</p> <p>8 well, let me strike that and back up.</p> <p>9 On your resume you indicate that you</p> <p>10 worked for CMS/CMSO.</p> <p>11 A. Correct.</p> <p>12 Q. Can you tell us what that means?</p> <p>13 A. Center for Medicaid and State Operations.</p> <p>14 Q. So as I understand it there are two broad</p> <p>15 divisions within CMS, one for Medicare and one for</p> <p>16 Medicaid; is that right?</p> <p>17 A. Correct.</p> <p>18 Q. And you worked in the Medicaid side?</p> <p>19 A. Correct.</p> <p>20 Q. Was that previously referred to as the</p> <p>21 Medicaid Bureau, do you know?</p> <p>22 A. At one time.</p>	<p>1 A. No.</p> <p>2 Q. I wanted to ask one other thing. From</p> <p>3 1991 to 2003, the previous job, did you work on</p> <p>4 federal upper limits?</p> <p>5 A. Yes.</p> <p>6 Q. And can you tell us what those are?</p> <p>7 A. The federal government sets an upper</p> <p>8 limit reimbursement amount on certain drugs.</p> <p>9 Q. What was the nature of your involvement</p> <p>10 with the federal upper limit program?</p> <p>11 A. I took care of setting the upper limit</p> <p>12 reimbursement amount on the drugs.</p> <p>13 Q. For all drugs?</p> <p>14 A. No. There were just -- the regulations</p> <p>15 indicate that they're set on -- there are certain</p> <p>16 criteria, and they're the drugs that we would set an</p> <p>17 upper limit reimbursement amount on.</p> <p>18 Q. I asked the wrong question. What I meant</p> <p>19 to ask was for drugs that HCFA did establish a</p> <p>20 federal upper limit, you would have been involved in</p> <p>21 that?</p> <p>22 A. Correct.</p>

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<p style="text-align: right;">Page 46</p> <p>1 Q. And did you work with anyone else in that</p> <p>2 area at HCFA?</p> <p>3 A. Yes.</p> <p>4 Q. Who else was involved in that?</p> <p>5 A. When I first started, Pete Rodler.</p> <p>6 MR. WINGET-HERNANDEZ: Could you spell it</p> <p>7 for us?</p> <p>8 THE WITNESS: Rodler, R-o-d-l-e-r.</p> <p>9 Q. Anyone else?</p> <p>10 A. Cindy Bergin. I mentored her later.</p> <p>11 Q. Her last name is spelled out?</p> <p>12 A. B-e-r-g-i-n.</p> <p>13 Q. Is she still with HCFA?</p> <p>14 A. Yes.</p> <p>15 Q. Is her name still Cindy Bergin?</p> <p>16 A. Yes.</p> <p>17 Q. Who else?</p> <p>18 A. That was it.</p> <p>19 Q. Can you recall anyone else during your</p> <p>20 time from 1991 to February of 2003 who was involved</p> <p>21 in the federal upper limit program?</p> <p>22 MS. MARTINEZ: Objection, form.</p>	<p style="text-align: right;">Page 48</p> <p>1 A. Relating to the work that I did on FULs?</p> <p>2 Q. Yes.</p> <p>3 MS. MARTINEZ: Objection, form.</p> <p>4 A. Only the people that I worked with, Pete</p> <p>5 Rodler or Cindy Bergin.</p> <p>6 MR. COOK: What is the nature of the form</p> <p>7 objection? Maybe I'm missing something.</p> <p>8 MS. MARTINEZ: Time period. Just for the</p> <p>9 record, I think you're only addressing during the</p> <p>10 1991 to 2003.</p> <p>11 MR. TORBORG: Correct.</p> <p>12 MS. MARTINEZ: And I just -- if that's</p> <p>13 the period of time that you're referring to I have</p> <p>14 no objection.</p> <p>15 MR. WINGET-HERNANDEZ: My objection was</p> <p>16 lack of foundation. I don't think you've</p> <p>17 established that there was anything called a FUL</p> <p>18 program.</p> <p>19 BY MR. TORBORG:</p> <p>20 Q. In your job today are you still working</p> <p>21 on issues relating to the FUL program?</p> <p>22 A. No.</p>
<p style="text-align: right;">Page 47</p> <p>1 Oh, you can answer. I make these little</p> <p>2 form objections. Don't worry.</p> <p>3 THE WITNESS: Okay.</p> <p>4 A. Not that I can remember.</p> <p>5 Q. What was the nature of Mr. Reed, your</p> <p>6 boss', involvement with the FULs, as we'll call</p> <p>7 them? Federal upper limits, FULs, is that correct?</p> <p>8 A. Correct.</p> <p>9 Q. What was the nature of his involvement in</p> <p>10 the FULs?</p> <p>11 A. Well, he had last say on anything that</p> <p>12 was sent out or published.</p> <p>13 Q. So did you discuss issues related to the</p> <p>14 FUL program with Mr. Reed?</p> <p>15 A. Yes.</p> <p>16 Q. Anyone else besides Mr. Reed you recall</p> <p>17 having discussions about the FUL program with?</p> <p>18 A. Can you be more specific with your</p> <p>19 question?</p> <p>20 Q. Is there anyone else within HCFA that you</p> <p>21 discussed issues relating to the federal upper limit</p> <p>22 program with?</p>	<p style="text-align: right;">Page 49</p> <p>1 Q. Do you know who's handling those issues</p> <p>2 today?</p> <p>3 A. Gail Sexton.</p> <p>4 Q. Anyone else?</p> <p>5 A. Not that I'm aware of.</p> <p>6 Q. Did you talk with anyone else about the</p> <p>7 federal upper limit program from April 1991 through</p> <p>8 February 2003 besides those within HCFA?</p> <p>9 A. When you say talk to anyone else --</p> <p>10 Q. About issues relating to the FUL program</p> <p>11 besides those within HCFA.</p> <p>12 MS. MARTINEZ: Objection, form.</p> <p>13 A. Do you mean for establishing the price --</p> <p>14 for doing --</p> <p>15 Q. Anything.</p> <p>16 A. For anything.</p> <p>17 Q. I'm starting broad and hope to narrow it</p> <p>18 down.</p> <p>19 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>20 MS. MARTINEZ: My objection is to the</p> <p>21 breadth, so you know. Difficult to answer.</p> <p>22 A. Yeah. I find it difficult to answer.</p>

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<p style="text-align: right;">Page 50</p> <p>1 There's times when I would call various states to go 2 ahead some feedback from them on availability of 3 drugs or various questions like that. 4 Q. Do you recall discussing issues relating 5 to the federal upper limit program with anyone else 6 besides those within HCFA and states, 7 representatives of states? 8 MS. MARTINEZ: Objection, form. 9 A. Here again, I'm not sure what you mean by 10 discussing. But I would call drug manufacturers to 11 verify pricing that's published in compendia. 12 Q. All right. Tell me about those 13 conversations. 14 MS. MARTINEZ: Objection, form. 15 Q. Who were they with and what you recall 16 being discussed? 17 MS. MARTINEZ: Objection, form. 18 A. I don't recall who it would be with. I 19 can just answer in general terms that if something 20 was questionable in the pricing compendia then we 21 would try to call the manufacturer to verify 22 availability.</p>	<p style="text-align: right;">Page 52</p> <p>1 information was current. 2 Q. Did you believe that the average 3 wholesale prices in the compendia represented the 4 average amount at which people could buy drugs from 5 wholesalers? 6 MS. MARTINEZ: Objection, form. 7 A. I couldn't make that statement. 8 Q. You weren't -- when you were having 9 conversations with drug manufacturers, you weren't 10 asking them something like is this the average price 11 at which you sell drugs to wholesalers? 12 A. No. 13 Q. Okay. As you probably have guessed 14 already, given the nature of this suit and where you 15 worked at CMS, my questions will largely focus on 16 the topic of state Medicaid programs payment to 17 providers for dispensing drugs to Medicaid 18 beneficiaries. Do you understand that topic? 19 A. Yes. 20 Q. As well as issues relating to the federal 21 upper limit program. In your experience at CMS what 22 was CMS's role when it came to the amounts that</p>
<p style="text-align: right;">Page 51</p> <p>1 Q. Did you discuss with drug manufacturers 2 anything other than availability of the drugs? 3 A. Sometimes we would try to verify the 4 price that's published in the compendia if it was 5 still current. 6 Q. And by price, are we talking about 7 average wholesale price or something more than that? 8 A. Average wholesale price, direct price or 9 wholesale acquisition cost. 10 Q. Do you recall any discussions with anyone 11 from Abbott Laboratories concerning pricing? 12 A. I don't recall. 13 Q. Why would you be making those contacts 14 with drug manufacturers? 15 A. To verify that the information in the 16 drug compendia was accurate in order to be able to 17 set an accurate federal upper limit amount. 18 Q. And when you say accurate, what do you 19 mean by that? 20 A. Following federal guidelines on setting 21 the upper limit reimbursement amount, we used the 22 compendia. So we wanted to make sure the</p>	<p style="text-align: right;">Page 53</p> <p>1 state Medicaid programs reimburse for drugs? 2 MS. MARTINEZ: Objection, form. 3 A. Could you explain your question? 4 Q. Yeah. What I'm trying to get is you 5 worked on what state Medicaid programs paid 6 providers for dispensing drugs. Is that right? 7 A. We looked at their state plan amendments. 8 That would have that information in there. 9 Q. Okay. Besides reviewing state plan 10 amendments what else did HCFA, now CMS, do when it 11 came to the topic of state Medicaid programs payment 12 for drugs? 13 MS. ALBEE: Objection. 14 MS. MARTINEZ: Objection, form. 15 A. Could you give me some more detail? 16 Q. I'm just trying to figure out what CMS's 17 role was when it came to what state Medicaid 18 programs paid for drugs, apart from approval of the 19 state plan amendments. 20 A. We would encourage the states to set 21 reimbursement amounts that follow federal guidelines 22 and that were reasonable and supportable.</p>

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<p>1 Q. And how did you encourage states to do 2 that?</p> <p>3 MS. MARTINEZ: Objection, form.</p> <p>4 Q. What was the nature of your acts in 5 encouraging the states to set reimbursement amounts 6 consistent with federal guidelines?</p> <p>7 A. We would provide that information in the 8 program releases. It's general guidance.</p> <p>9 Q. Were you involved in any conversations, 10 in-face meetings or phone calls with states to 11 encourage them to set reimbursement amounts 12 consistent with federal guidelines?</p> <p>13 MS. MARTINEZ: Objection, form.</p> <p>14 A. I can't specifically remember particular 15 conversations. I would assume that a conversation 16 like that would occur if you're discussing a state 17 plan amendment with a state.</p> <p>18 Q. And you recall having discussions with 19 representatives from states concerning state plan 20 amendments; is that right?</p> <p>21 A. Correct.</p> <p>22 Q. Were those conversations typically over</p>	<p>1 Q. Code of federal --</p> <p>2 A. Yes.</p> <p>3 Q. This is a broad question. I'm sure we'll 4 get into it more today. But did you find it 5 difficult to get states to reimburse at amounts 6 consistent with federal regulations?</p> <p>7 MS. ALBEE: Objection.</p> <p>8 MS. MARTINEZ: Objection, form.</p> <p>9 A. Generally, no.</p> <p>10 Q. And there are -- as I understand it, 11 there is a regulation for federal upper limits, 12 correct?</p> <p>13 A. Correct.</p> <p>14 Q. As well as a regulation that governs the 15 payments for all other drugs?</p> <p>16 A. Correct.</p> <p>17 Q. And those to your understanding would be 18 drugs that are not covered by the federal upper 19 limit program; is that right?</p> <p>20 A. That's my understanding.</p> <p>21 Q. It could be sole source drugs or multiple 22 source drugs; is that right?</p>
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<p>1 the phone or were they in person?</p> <p>2 A. Generally over the phone.</p> <p>3 Q. And did you have a set territory of the 4 country or a certain number of states that you were 5 involved with with state plan amendments?</p> <p>6 A. I don't recall exactly. I think at one 7 time we had particular states that we serviced. But 8 I don't recall what states they were or what period 9 of time that occurred.</p> <p>10 Q. Did you have primary authority for a 11 certain number of states and then backup 12 responsibility for other states? Is that how it 13 worked?</p> <p>14 MS. MARTINEZ: Objection, form.</p> <p>15 A. From what I remember, during a period of 16 time that's how we processed the state plan 17 amendments.</p> <p>18 Q. And you referred to federal guidelines. 19 What did you mean by that?</p> <p>20 A. Federal regulations.</p> <p>21 Q. Which regulations did you have in mind?</p> <p>22 A. The regulations in the C.F.R.</p>	<p>1 A. Yes.</p> <p>2 Q. Did you find it difficult to -- let me 3 strike that.</p> <p>4 And the regulation governing all other 5 drugs not covered by a FUL required the states to 6 reimburse drugs such that in the aggregate they were 7 reimbursing at their best estimate of what providers 8 could generally and currently purchase those drugs 9 in the marketplace; is that right?</p> <p>10 MS. MARTINEZ: Objection, form.</p> <p>11 A. Are you saying that's not for federal 12 upper limit?</p> <p>13 Q. Yes. There's a regulation that covers 14 drugs that are within the federal upper limit, 15 correct?</p> <p>16 A. Correct.</p> <p>17 Q. And there's a regulation that covers 18 drugs that are not covered by the federal upper 19 limit?</p> <p>20 A. Correct.</p> <p>21 MR. WINGET-HERNANDEZ: Objection to form.</p> <p>22 Q. Correct?</p>

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<p style="text-align: right;">Page 58</p> <p>1 A. Correct.</p> <p>2 Q. And what is the regulation covering drugs</p> <p>3 not covered by the upper limit program?</p> <p>4 MS. MARTINEZ: Objection, form.</p> <p>5 Q. Do you know that?</p> <p>6 A. You mean the methodology in the</p> <p>7 regulation?</p> <p>8 Q. Yes.</p> <p>9 A. You're asking me to repeat that?</p> <p>10 Q. Your understanding of what it is.</p> <p>11 A. Generally it's the lower of the estimated</p> <p>12 acquisition cost or what is generally paid -- here</p> <p>13 again, I'm not going to remember the exact words,</p> <p>14 and I haven't been working in that area for a while.</p> <p>15 But it's either the estimated acquisition cost or</p> <p>16 the cost that's to the general public. I can't</p> <p>17 remember exactly what it is. But it's in the</p> <p>18 regulation.</p> <p>19 What you were talking about before in the</p> <p>20 aggregate sounded more like what's in the federal</p> <p>21 upper limit regulation.</p> <p>22 Q. Okay. We'll look at the regulations in</p>	<p style="text-align: right;">Page 60</p> <p>1 time ago; is that fair to say?</p> <p>2 A. Correct.</p> <p>3 Q. And your recollection has -- you've</p> <p>4 forgotten some things; is that fair to say?</p> <p>5 A. Very -- yes.</p> <p>6 Q. You were going to say something about</p> <p>7 "very"?</p> <p>8 A. My recollection, yes. No. I'm agreeing</p> <p>9 with you.</p> <p>10 Q. It's very much diminished; is that fair</p> <p>11 to say?</p> <p>12 MS. MARTINEZ: Objection, form.</p> <p>13 A. I can't remember everything.</p> <p>14 Q. Do you think there are a lot of things, a</p> <p>15 lot of detail, that you don't remember?</p> <p>16 A. Maybe.</p> <p>17 MS. MARTINEZ: Objection.</p> <p>18 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>19 Q. Ms. Gaston, do you belong to any</p> <p>20 professional organizations?</p> <p>21 A. No.</p> <p>22 Q. Have you attended in the past meetings or</p>
<p style="text-align: right;">Page 59</p> <p>1 particular later. Do you recall having difficulty</p> <p>2 getting states to abide by the federal regulations</p> <p>3 covering drugs not covered by the federal upper</p> <p>4 limit program?</p> <p>5 MS. MARTINEZ: Objection, form.</p> <p>6 A. No. Generally not.</p> <p>7 Q. You don't recall any difficulties with</p> <p>8 that at all?</p> <p>9 A. I can't recall specifically.</p> <p>10 Q. You don't recall that being a discussion</p> <p>11 within your office?</p> <p>12 MS. MARTINEZ: Objection, form.</p> <p>13 A. Can you explain --</p> <p>14 Q. The difficulty getting states to set a</p> <p>15 reimbursement methodology for drugs not covered by</p> <p>16 the federal upper limit program so that it met</p> <p>17 federal regulations?</p> <p>18 MS. MARTINEZ: Objection, form.</p> <p>19 A. I'm sure that it was discussed. I don't</p> <p>20 remember the specifics, when, or exactly what was</p> <p>21 discussed.</p> <p>22 Q. And some of these events took place some</p>	<p style="text-align: right;">Page 61</p> <p>1 seminars relating to state Medicaid pharmacy issues?</p> <p>2 MS. MARTINEZ: Objection, form.</p> <p>3 A. Can you be more specific? Do you have</p> <p>4 any examples?</p> <p>5 Q. I've heard meetings held of the PTAG,</p> <p>6 Pharmacy Technical Advice Commission, or whatever it</p> <p>7 is. I can't remember what it is. Group.</p> <p>8 A. It's been a long time since I've been to</p> <p>9 a PTAG meeting.</p> <p>10 Q. But you've attended PTAG meetings in the</p> <p>11 past?</p> <p>12 A. Yes.</p> <p>13 Q. Have you attended any other meetings</p> <p>14 where the issue of state pharmacy payment was</p> <p>15 discussed?</p> <p>16 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>17 A. And are you saying any period of time or</p> <p>18 a specific period of time?</p> <p>19 Q. 1991 through 2001.</p> <p>20 A. Yes.</p> <p>21 Q. What other meetings do you recall</p> <p>22 attending?</p>

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<p style="text-align: right;">Page 62</p> <p>1 A. Some of the pharmacy associations have</p> <p>2 meetings. I attended one in Boston. They're more</p> <p>3 or less conferences. I think one was in Raleigh,</p> <p>4 North Carolina.</p> <p>5 Q. When you say pharmacy association, what</p> <p>6 is that? Is that a group of pharmacists or a group</p> <p>7 of state people, state administrators, who work in</p> <p>8 the pharmacy area?</p> <p>9 A. It's my recollection they were state</p> <p>10 pharmacy folks and then some manufacturers would</p> <p>11 also attend.</p> <p>12 Q. Was the topic of average wholesale price</p> <p>13 discussed at those meetings?</p> <p>14 A. I can't recall.</p> <p>15 Q. Did you receive any materials at those</p> <p>16 meetings?</p> <p>17 A. I may have.</p> <p>18 Q. Did you keep those?</p> <p>19 A. No.</p> <p>20 Q. Do you recall what type of topics were</p> <p>21 discussed at the meetings of the state pharmacy</p> <p>22 personnel?</p>	<p style="text-align: right;">Page 64</p> <p>1 A. There may have been.</p> <p>2 Q. You just can't recall those given the</p> <p>3 passage of time; is that fair to say?</p> <p>4 MS. MARTINEZ: Objection, form.</p> <p>5 A. Correct.</p> <p>6 Q. At the meetings that you recall, was the</p> <p>7 issue of adequacy of dispensing fees ever discussed?</p> <p>8 MS. MARTINEZ: Objection, form.</p> <p>9 A. I can't recall.</p> <p>10 Q. And do you know what I'm asking you about</p> <p>11 there with the adequacy of dispensing fee?</p> <p>12 A. Do I know --</p> <p>13 Q. Yeah. You know what I'm talking about?</p> <p>14 A. Yes, I do.</p> <p>15 Q. The dispensing fee is what?</p> <p>16 A. That it's reasonable.</p> <p>17 Q. Is that a topic that you recall coming up</p> <p>18 quite a bit during your time at CMS?</p> <p>19 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>20 MS. ALBEE: Objection, form.</p> <p>21 MS. MARTINEZ: Objection, form.</p> <p>22 A. The issue comes up in the discussion of</p>
<p style="text-align: right;">Page 63</p> <p>1 MS. MARTINEZ: Objection, form.</p> <p>2 A. I do remember that some of the states</p> <p>3 that are present, they would go around the table</p> <p>4 just talking about what's happening in their states</p> <p>5 relating to their Medicaid programs. I presented at</p> <p>6 those conferences discussing various issues</p> <p>7 concerning the rebate program.</p> <p>8 Q. Did you keep any materials relating to</p> <p>9 that, to your presentations?</p> <p>10 A. No.</p> <p>11 Q. Did you prepare any materials for these</p> <p>12 presentations?</p> <p>13 A. Yes.</p> <p>14 Q. Do you recall any other meetings that</p> <p>15 you've had apart from meetings with state pharmacy</p> <p>16 personnel and the PTAG group at which the issue of</p> <p>17 state pharmacy payment for drugs was discussed?</p> <p>18 MS. MARTINEZ: Objection, form.</p> <p>19 A. I can't specifically remember any</p> <p>20 particular meetings.</p> <p>21 Q. But you believe that there may have been</p> <p>22 others?</p>	<p style="text-align: right;">Page 65</p> <p>1 state plan amendments, but other than that I don't</p> <p>2 recall it being a big issue.</p> <p>3 Q. And how does it come up in the context of</p> <p>4 state plan amendments?</p> <p>5 A. Because in the state plan amendment</p> <p>6 generally states will have something in there about</p> <p>7 their dispensing fee. And then they have to provide</p> <p>8 sufficient documentation or justification for their</p> <p>9 dispensing fee.</p> <p>10 Q. Do you recall there being discussion that</p> <p>11 the dispensing fee as set by the states was not</p> <p>12 adequate to cover a pharmacy's cost?</p> <p>13 MS. MARTINEZ: Objection, form.</p> <p>14 A. Can you repeat that?</p> <p>15 MR. TORBORG: Would you mind reading it</p> <p>16 back, Jon?</p> <p>17 (Whereupon, the requested portion was</p> <p>18 read by the reporter.)</p> <p>19 A. I don't recall specific conversations.</p> <p>20 Q. And is that because of the passage of</p> <p>21 time?</p> <p>22 MR. WINGET-HERNANDEZ: Objection, form.</p>

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<p>1 A. Correct.</p> <p>2 Q. Did you attend meetings with the Office</p> <p>3 of Inspector General relating to state pharmacy</p> <p>4 issues?</p> <p>5 A. Yes.</p> <p>6 Q. Can you approximate how many such</p> <p>7 meetings you've attended?</p> <p>8 A. No, I could not.</p> <p>9 Q. More than five?</p> <p>10 A. I really can't recall.</p> <p>11 Q. Do you recall who you met with at OIG?</p> <p>12 A. Ben Jackson. From Little Rock I think</p> <p>13 there were two individuals from Little Rock, but I</p> <p>14 can't remember their names at this time.</p> <p>15 Q. Paul Chesser? Is that --</p> <p>16 A. Correct.</p> <p>17 Q. Was he from Little Rock?</p> <p>18 A. Correct. It's my understanding.</p> <p>19 Q. Gordon Sato. Does that sound familiar?</p> <p>20 A. That name does not sound familiar.</p> <p>21 Q. No?</p> <p>22 A. No.</p>	<p>1 Q. Do you remember meeting with a woman by</p> <p>2 the name of Linda Ragone?</p> <p>3 A. That name doesn't sound familiar.</p> <p>4 Q. Did you review any professional</p> <p>5 literature in connection with your job, Ms. Gaston?</p> <p>6 A. Can you be more specific?</p> <p>7 Q. Magazine articles, things of that nature.</p> <p>8 A. Generally no.</p> <p>9 Q. Is it fair to say that from April 1991</p> <p>10 through February of 2003 your job was focused on</p> <p>11 pharmacy-related issues? Is that right?</p> <p>12 A. Correct.</p> <p>13 Q. And did you review any publications</p> <p>14 relating to pharmacy issues?</p> <p>15 A. Yes.</p> <p>16 Q. Which ones do you recall reviewing?</p> <p>17 A. The Pink Sheets -- and you're talking</p> <p>18 about that specific time?</p> <p>19 Q. Yes. Did your office have a subscription</p> <p>20 to Pink Sheets?</p> <p>21 A. Yes.</p> <p>22 Q. Did other people in the office read it?</p>
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<p>1 Q. How about William Shrigley?</p> <p>2 A. Yes.</p> <p>3 MS. MARTINEZ: I'm sorry. Was your</p> <p>4 question does she recall that name or does she</p> <p>5 recall meeting with Mr. Shrigley?</p> <p>6 Q. Do you recall meeting with Mr. Shrigley?</p> <p>7 A. Yes.</p> <p>8 Q. Anyone else?</p> <p>9 A. I can't recall any other names at this</p> <p>10 time.</p> <p>11 Q. Did you ever meet with a Mr. Robert Vito?</p> <p>12 A. Yes.</p> <p>13 Q. Do you recall the nature of that meeting</p> <p>14 at all?</p> <p>15 A. No, I don't recall.</p> <p>16 Q. How about David Tawes? Do you remember</p> <p>17 meeting with him?</p> <p>18 A. Yes.</p> <p>19 Q. Do you recall the nature of your</p> <p>20 discussions with him?</p> <p>21 A. It might have been for a federal upper</p> <p>22 limit OIG report or study they were doing.</p>	<p>1 A. Yes.</p> <p>2 MS. MARTINEZ: Objection, form.</p> <p>3 Q. Did you circulate interesting articles</p> <p>4 from Pink Sheets around the office?</p> <p>5 MS. MARTINEZ: Objection, form.</p> <p>6 A. The Pink Sheet was circulated around the</p> <p>7 office.</p> <p>8 Q. Any other publications you recall</p> <p>9 reviewing?</p> <p>10 A. I can't recall other publications.</p> <p>11 Q. How about Drug Topics? Did you ever</p> <p>12 review that one?</p> <p>13 A. It sounds familiar, but I don't remember.</p> <p>14 Q. How about Eli's Home Week? Do you recall</p> <p>15 that publication?</p> <p>16 A. I don't recall that.</p> <p>17 Q. How about Modern Health Care?</p> <p>18 A. I don't recall that.</p> <p>19 Q. How about something called the Medicaid</p> <p>20 Pharmacy Bulletin?</p> <p>21 A. That sounds familiar, but I don't recall</p> <p>22 the bulletin.</p>

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<p>1 Q. Do you recall if your office had a</p> <p>2 subscription to that publication?</p> <p>3 A. I don't know.</p> <p>4 MR. TORBORG: Why don't we take a ten</p> <p>5 minute break here.</p> <p>6 THE VIDEOGRAPHER: This is the end of</p> <p>7 tape 1. Off the record at 10:32.</p> <p>8 (Recess.)</p> <p>9 THE VIDEOGRAPHER: This is the beginning</p> <p>10 of tape 2 in the deposition of Ms. Gaston. On the</p> <p>11 record at 10:47.</p> <p>12 BY MR. TORBORG:</p> <p>13 Q. Welcome back, Ms. Gaston. Did you do</p> <p>14 anything to prepare for today's deposition?</p> <p>15 A. Yes.</p> <p>16 Q. Did you meet with counsel?</p> <p>17 A. Yes.</p> <p>18 Q. Did you do anything else to prepare for</p> <p>19 today's deposition other than meet with counsel?</p> <p>20 A. Could you explain what you mean?</p> <p>21 Q. Did you review any documents, anything</p> <p>22 else that you did to get ready for today?</p>	<p>1 Q. Either in that session, the other session</p> <p>2 or otherwise, have you reviewed any documents to</p> <p>3 refresh your recollection to prepare for this</p> <p>4 deposition?</p> <p>5 A. No.</p> <p>6 Q. You indicated you met with counsel</p> <p>7 another time, correct? How long was the other</p> <p>8 meeting?</p> <p>9 A. A couple hours.</p> <p>10 Q. That was in person?</p> <p>11 A. Yes.</p> <p>12 Q. Have you discussed the fact that you're</p> <p>13 being deposed with anyone else besides counsel?</p> <p>14 A. Yes.</p> <p>15 Q. Who?</p> <p>16 A. My division director.</p> <p>17 Q. Who is that?</p> <p>18 A. Rick Friedman.</p> <p>19 Q. Do you know that others at CMS have been</p> <p>20 deposed in this litigation?</p> <p>21 A. Yes.</p> <p>22 Q. Who are you aware of who's been deposed?</p>
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<p>1 A. No.</p> <p>2 Q. Who did you meet with?</p> <p>3 A. I met with Ani and Leslie.</p> <p>4 Q. And when was that meeting or meetings?</p> <p>5 A. Last Friday. I don't have the date. And</p> <p>6 one other time. I don't know which date that was.</p> <p>7 Q. Was it before last Friday or after last</p> <p>8 Friday?</p> <p>9 A. Before last Friday.</p> <p>10 Q. And do you recall how long the initial</p> <p>11 meeting was approximately?</p> <p>12 A. I'm just thinking about last Friday. I</p> <p>13 could be wrong. It was a Friday. I think it was</p> <p>14 last Friday. But I could ask Ani what date it was.</p> <p>15 Q. Okay.</p> <p>16 A. Do you want me to do that?</p> <p>17 Q. No. It's not necessary. How long did</p> <p>18 you meet last Friday?</p> <p>19 A. About three hours.</p> <p>20 Q. Did you review any documents in that</p> <p>21 meeting?</p> <p>22 A. No.</p>	<p>1 A. Larry Reed, Deirdra Duzor.</p> <p>2 Q. Anyone else?</p> <p>3 A. No.</p> <p>4 Q. Have you discussed those depositions with</p> <p>5 either of those people?</p> <p>6 A. No.</p> <p>7 Q. Have you discussed the substance of their</p> <p>8 testimony in anywhere way with counsel?</p> <p>9 MS. MARTINEZ: Objection.</p> <p>10 Q. For example, did counsel indicate, well,</p> <p>11 Mr. Reed said this or anything of that nature?</p> <p>12 A. No.</p> <p>13 MS. MARTINEZ: Counsel, asking</p> <p>14 specifically about discussions with counsel is</p> <p>15 privileged.</p> <p>16 MR. TORBORG: I'm not asking for the</p> <p>17 contents of the discussion.</p> <p>18 MS. MARTINEZ: Yes, you are.</p> <p>19 MR. TORBORG: No. I didn't ask about the</p> <p>20 content. Listen to the question carefully.</p> <p>21 MR. WINGET-HERNANDEZ: Objection to the</p> <p>22 form.</p>

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<p style="text-align: right;">Page 74</p> <p>1 MS. MARTINEZ: Object to the form. She 2 answered the question. I'm just saying if you put 3 the content in your question and then ask did you 4 talk about this then you are asking about the 5 content of a discussion with counsel. 6 BY MR. TORBORG: 7 Q. Prior to the meetings you've had with 8 counsel, Ms. Gaston, have you had any other 9 discussions with any lawyers on the subject of AWP 10 or Medicaid payment for drugs? 11 A. Could you give me more detail? 12 Q. I'm just asking if you've had any -- 13 apart from these meetings preparing for this 14 deposition, have you had any other meetings with 15 attorneys concerning the subject of average 16 wholesale price or Medicaid reimbursement of drugs? 17 MS. MARTINEZ: Objection, form. 18 A. Do you have like a specific period of 19 time? Anytime? 20 Q. Not at this point. I'm just asking if 21 there are any. It sounds like there may be. 22 A. There may have been. But I don't know</p>	<p style="text-align: right;">Page 76</p> <p>1 Q. Do you have any recollection regarding 2 the general nature of those conversations? 3 MR. WINGET-HERNANDEZ: Objection, form. 4 MS. MARTINEZ: Objection, form. 5 A. I can't say. 6 Q. You can't say at all what you may have 7 talked about with attorneys; is that right? 8 MS. MARTINEZ: Objection, form. 9 A. Your question is too broad. I'd have to 10 know specifically what an issue would have been. 11 And here again, I don't recall those specific 12 conversations. So it's hard for me to give you an 13 answer on that. 14 Q. And my question is more general than 15 that. And that is, do you recall the general 16 subject matter of any conversations that you've had 17 with counsel? 18 MS. MARTINEZ: Objection, form. 19 A. I don't know how to answer that. I need 20 something more from you. I don't know where you're 21 going with it. If you could explain what you're 22 saying.</p>
<p style="text-align: right;">Page 75</p> <p>1 specifically. 2 Q. Why do you believe there may have been? 3 A. Because that would be a subject when I 4 worked in policy that was something that could have 5 been discussed with our general counsel. 6 Q. Who is your general counsel? 7 A. Mary Salhus. 8 Q. Have you provided -- do you recall in any 9 of those discussions have you provided any factual 10 information to counsel? 11 MR. WINGET-HERNANDEZ: Objection, form. 12 A. I don't remember those specific 13 discussions. 14 Q. Do you recall providing -- it sounds like 15 you recall there may have been some general 16 discussions in the course of your work. Is that 17 right? 18 MS. MARTINEZ: Objection, form. 19 A. The reason I'm saying that is because of 20 the nature of the work in policy, that those 21 discussions could have occurred. But I don't 22 remember any of those specific discussions.</p>	<p style="text-align: right;">Page 77</p> <p>1 Q. I'm trying to figure out just if you've 2 had discussions with counsel what the nature of the 3 discussions was. That's all I'm trying to figure 4 out. 5 MS. MARTINEZ: Objection to form. 6 A. It could have been anything. We discuss 7 a lot of things with counsel in policy. It could 8 have been concerning a state plan amendment. It 9 could -- it's -- I don't know specifically, so I 10 can't be that specific in my response. 11 Q. Have you ever discussed litigation 12 related to average wholesale price with the 13 Department of Justice? 14 MS. MARTINEZ: Objection, form. 15 A. I don't recall. If they were involved 16 in -- if they were involved in the other deposition, 17 which I don't think they were, or if they were 18 involved with the grand jury, I'm not sure. So I 19 really can't say that it occurred. 20 Q. Ms. Gaston, do you understand that you're 21 here today in connection with lawsuit that the 22 United States Government has brought against Abbott</p>

20 (Pages 74 to 77)

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<p style="text-align: right;">Page 78</p> <p>1 Laboratories?</p> <p>2 A. Yes.</p> <p>3 Q. Do you have an understanding of what the</p> <p>4 United States alleges that Abbott did wrong?</p> <p>5 A. I have a basic understanding.</p> <p>6 Q. What is your basic understanding?</p> <p>7 A. My basic understanding is there's</p> <p>8 concerns that there were certain drugs that the</p> <p>9 prices of those particular drugs may be higher than</p> <p>10 what they should be for purposes of reimbursement.</p> <p>11 Q. Do you have an understanding of what</p> <p>12 prices in particular are at issue?</p> <p>13 A. What do you mean by what prices?</p> <p>14 Q. Average wholesale price, things like</p> <p>15 that.</p> <p>16 A. Average wholesale price I think is one of</p> <p>17 the issues.</p> <p>18 Q. Do you have an understanding of -- when</p> <p>19 you say that the prices for certain drugs were</p> <p>20 higher than they should be, do you have an</p> <p>21 understanding of what it is the government contends</p> <p>22 they should have been?</p>	<p style="text-align: right;">Page 80</p> <p>1 peruse that, Ms. Gaston, my question will be whether</p> <p>2 or not you have ever seen this document before.</p> <p>3 A. I don't recall seeing this. I don't</p> <p>4 recall seeing this document.</p> <p>5 Q. Let me ask you to go to page 10 of the</p> <p>6 complaint. Specifically paragraph 31. There's --</p> <p>7 after the first paragraph there's a couple columns</p> <p>8 titled drug and NDC. Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. And there are some various NDC numbers</p> <p>11 listed. Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. Included within here are NDCs for sodium</p> <p>14 chloride, water for injection, vancomycin and then</p> <p>15 some dextrose-type solutions. Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. Does that refresh your recollection at</p> <p>18 all regarding what types of drugs are at issue in</p> <p>19 this case?</p> <p>20 A. I guess I don't -- it's not that I don't</p> <p>21 remember what drugs were included in this case --</p> <p>22 Q. You've never known?</p>
<p style="text-align: right;">Page 79</p> <p>1 A. No.</p> <p>2 Q. Do you have an understanding of the</p> <p>3 nature of the drugs at issue in this case?</p> <p>4 A. You mean what type of drugs?</p> <p>5 Q. Yes. The type of drugs.</p> <p>6 A. In the Abbott case?</p> <p>7 Q. Yes.</p> <p>8 A. I think they're just injectables.</p> <p>9 Q. And when you say injectables, what do you</p> <p>10 mean by that?</p> <p>11 A. Drugs that are injectables. They're not</p> <p>12 tablets or capsules.</p> <p>13 Q. Do you know which specific injectables</p> <p>14 are at issue?</p> <p>15 A. No, I don't.</p> <p>16 Q. I'd like to ask you to take out Exhibit</p> <p>17 19 in those binders there, Ms. Gaston. Were you</p> <p>18 able to find it, Ms. Gaston?</p> <p>19 A. Yes.</p> <p>20 Q. For the record, Exhibit 19 is a copy of</p> <p>21 the initial complaint filed by the United States</p> <p>22 against Abbott Labs. After you've had a chance to</p>	<p style="text-align: right;">Page 81</p> <p>1 A. -- I really don't -- I'm not aware of --</p> <p>2 I may have read it, but I don't remember which drugs</p> <p>3 were included in this case. So this doesn't really</p> <p>4 refresh my memory. I just don't remember</p> <p>5 specifically which drugs are included in this case.</p> <p>6 MS. MARTINEZ: And just for the record,</p> <p>7 I mean, there is an amended complaint that the</p> <p>8 United States filed that includes an additional</p> <p>9 drug, acyclovir.</p> <p>10 MR. TORBORG: An additional NDC?</p> <p>11 MS. MARTINEZ: An additional drug and</p> <p>12 NDC, yeah. Right. An injectable version of</p> <p>13 acyclovir.</p> <p>14 MR. TORBORG: Well, that complaint is</p> <p>15 still pending before Judge Saris whether or not you</p> <p>16 can file that, but --</p> <p>17 MS. MARTINEZ: You mean your motion to</p> <p>18 dismiss is pending. The complaint has been filed.</p> <p>19 MR. TORBORG: The motion for lead is also</p> <p>20 pending.</p> <p>21 BY MR. TORBORG:</p> <p>22 Q. Ms. Gaston, regardless of whether or not</p>

21 (Pages 78 to 81)

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<p style="text-align: right;">Page 82</p> <p>1 you are familiar with these particular -- or that</p> <p>2 you knew these NDCs were at issue in the case, have</p> <p>3 you run across these drugs in your work at all?</p> <p>4 A. I may have. I don't specifically</p> <p>5 remember.</p> <p>6 Q. You don't recall any specific issues</p> <p>7 arising with any of these drugs?</p> <p>8 A. Specifically, I can't remember.</p> <p>9 Q. Do you know how these drugs are dispensed</p> <p>10 to Medicaid beneficiaries?</p> <p>11 A. You mean how -- can you explain yourself?</p> <p>12 Q. Do you know how these drugs are dispensed</p> <p>13 by providers to Medicaid beneficiaries such that the</p> <p>14 Medicaid program would reimburse them?</p> <p>15 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>16 A. Are you asking are they provided in a</p> <p>17 pharmacy or a physician's office or --</p> <p>18 Q. Correct. That's what I'm getting at.</p> <p>19 Yes.</p> <p>20 A. Okay. I wouldn't know specifically how</p> <p>21 they're dispensed.</p> <p>22 Q. Do you know what types of providers would</p>	<p style="text-align: right;">Page 84</p> <p>1 A. No. I would not know.</p> <p>2 Q. I'm going to ask you to go to paragraph</p> <p>3 38 of the initial complaint. Do you see there it</p> <p>4 says "No governmental payor knew of or sanctioned</p> <p>5 Abbott's conduct as set forth in this complaint;</p> <p>6 i.e., its deliberate manipulation of its published</p> <p>7 prices for certain of its products to induce the</p> <p>8 customers to purchase those products."</p> <p>9 Ms. Gaston, were you asked whether or not</p> <p>10 you personally were aware of whether or not</p> <p>11 published prices were consistent with acquisition</p> <p>12 cost?</p> <p>13 MS. MARTINEZ: Objection, form.</p> <p>14 Q. Have you ever been asked that question?</p> <p>15 A. Can you repeat that?</p> <p>16 Q. Have you ever done asked during your time</p> <p>17 at CMS whether or not you knew that published prices</p> <p>18 did not equal acquisition costs?</p> <p>19 MS. MARTINEZ: Objection, form.</p> <p>20 Q. Is that a topic that has come up in</p> <p>21 conversations?</p> <p>22 MS. MARTINEZ: Objection, form.</p>
<p style="text-align: right;">Page 83</p> <p>1 have submitted claims to seek reimbursement for</p> <p>2 these NDCs?</p> <p>3 A. No. I would not know.</p> <p>4 Q. Do you know why the government decided to</p> <p>5 bring suit regarding these particular drugs?</p> <p>6 A. It's my understanding that the suit is</p> <p>7 because the federal government is concerned about</p> <p>8 the prices that -- the prices that the</p> <p>9 manufacturer -- they felt that the prices were</p> <p>10 higher on some of the drugs for reimbursement</p> <p>11 purposes.</p> <p>12 Q. Higher than what?</p> <p>13 A. Than what I guess they felt was</p> <p>14 reasonable.</p> <p>15 Q. Do you have a view on what price would be</p> <p>16 reasonable, Ms. Gaston?</p> <p>17 A. You mean a specific price?</p> <p>18 Q. Generally.</p> <p>19 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>20 Q. Across drugs.</p> <p>21 A. Are you saying a money amount?</p> <p>22 Q. A money amount, yeah.</p>	<p style="text-align: right;">Page 85</p> <p>1 A. When you say the estimated acquisition</p> <p>2 cost, do you mean -- okay. What do you mean by</p> <p>3 that? Do you mean what the states are paying?</p> <p>4 Q. No. I'm asking what providers are paying</p> <p>5 for the drugs.</p> <p>6 MS. MARTINEZ: Objection, form.</p> <p>7 A. So that's what the state --</p> <p>8 Q. Let me back up and try this a different</p> <p>9 way.</p> <p>10 A. Okay.</p> <p>11 Q. Do you understand what damages the</p> <p>12 government is seeking in this case?</p> <p>13 A. What do you mean damages?</p> <p>14 Q. You know in civil litigation someone is</p> <p>15 suing for an amount of money.</p> <p>16 A. Okay.</p> <p>17 Q. Do you know generally speaking -- not</p> <p>18 numbers -- what types of damages the government is</p> <p>19 seeking in this case?</p> <p>20 A. No, I don't.</p> <p>21 Q. Are you familiar with the term "spread"</p> <p>22 as used in the context of pharmacy issues.</p>

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<p style="text-align: right;">Page 86</p> <p>1 A. I've heard the term. I'm not really 2 familiar with it. 3 Q. When have you used the term? 4 A. It just sounds familiar to me. I don't 5 know when. 6 Q. You don't know what the term the spread 7 means in connection with prescription drugs? 8 A. It's really not a term that I use. 9 Q. We sent you a subpoena for your 10 appearance here today. Did you see that? 11 A. Yes. 12 Q. It called for certain types of documents 13 in your personal possession? 14 A. Yes. 15 Q. Did you make a search of your personal 16 files for any such documents? 17 A. Yes. 18 Q. Did you have any? 19 A. Whatever I had was previously obtained by 20 counsel. I have no other further documents. 21 Q. Did you have documents at your home or -- 22 A. No.</p>	<p style="text-align: right;">Page 88</p> <p>1 of those paper files? 2 A. I really can't remember. 3 Q. Was it one box, five boxes, a file 4 cabinet? Do you have any idea? 5 A. It wouldn't be a file cabinet. It would 6 be less than a file cabinet. Yeah. A couple 7 folders, from my recollection. 8 Q. And were those documents turned over to 9 counsel in response to discovery taken in this or 10 another case? 11 A. Those documents -- the ones that I'm 12 referencing are the ones for the period of time when 13 I worked in policy. And they stayed in the policy 14 area when I moved in 2003. 15 Q. So you had possession of the files prior 16 to 2003 in your cube? 17 A. Correct. 18 Q. And then after you moved over to the new 19 office you left those behind? 20 A. Correct. 21 Q. Did you switch offices in your new job? 22 A. Yes.</p>
<p style="text-align: right;">Page 87</p> <p>1 Q. -- in your car? 2 A. No. 3 Q. Did you have documents in your office 4 relating to -- that would have been responsive to 5 the subpoena? 6 A. To the subpoena? 7 Q. Yes. 8 A. No. 9 Q. Did you have your own office at HCFA from 10 1991 through 2001? 11 A. I had a cube. 12 Q. And what types of -- did you have files 13 that related to the FUL program? 14 A. Yes. 15 Q. What types of files did you have? Can 16 you describe them for me? 17 A. You mean the paper that -- I mean, they 18 were just files. They were paperwork. They might 19 have been correspondence, copies of the old FUL 20 publications. It could have been any kind of 21 general information, correspondence. 22 Q. Can you give me an idea for the magnitude</p>	<p style="text-align: right;">Page 89</p> <p>1 Q. You referred to something called the 2 policy area. What is that? 3 A. That was where I worked from '91 through 4 2003. 5 Q. And do you know specifically where your 6 files relating to the federal upper limit program 7 went? 8 A. No. 9 Q. Did you have files at your previous job, 10 the policy job, relating to approval of state plans, 11 state plan amendments? 12 A. Yes. 13 Q. And did you take those with you when you 14 switched jobs? 15 A. No. 16 Q. So those are back somewhere in the policy 17 area? 18 MS. MARTINEZ: Objection, form. 19 A. Yeah. As far as I know. I don't know 20 where they are now. 21 Q. When you switched office did you have to 22 sign out your files or put them someplace like in an</p>

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<p>1 archives or something like that?</p> <p>2 A. No.</p> <p>3 Q. Or just leave them behind in your office</p> <p>4 and move on?</p> <p>5 A. I left them behind.</p> <p>6 Q. You don't know who they went to?</p> <p>7 A. No.</p> <p>8 Q. Can you give me a sense for the volume of</p> <p>9 documents you had relating to approval of state plan</p> <p>10 amendments?</p> <p>11 A. I really wouldn't have any idea.</p> <p>12 Q. Would it be a file cabinet?</p> <p>13 A. If -- probably less than that.</p> <p>14 Q. Compared to the volume of the federal</p> <p>15 upper limit documents, more or less?</p> <p>16 A. That's really hard to say.</p> <p>17 Q. Did you have any documents -- when you</p> <p>18 switched jobs, did you keep the same computer or did</p> <p>19 you switch? Files that were on your hard drive</p> <p>20 originally, did they stay there?</p> <p>21 A. Correct.</p> <p>22 Q. So you still had access to all the same</p>	<p>1 was probably -- I can't remember the date on the</p> <p>2 document. But we received it and it was asking us</p> <p>3 to not destroy any documents.</p> <p>4 Q. Related to what subject?</p> <p>5 A. I can't remember.</p> <p>6 Q. Did you get this notice while you were</p> <p>7 working in the new position?</p> <p>8 A. Yes.</p> <p>9 Q. Was it a notice you received within the</p> <p>10 last year or prior to that?</p> <p>11 A. Prior to that.</p> <p>12 Q. Prior to getting that document hold</p> <p>13 notice did you make any efforts to keep documents</p> <p>14 that might relate to Medicaid payment for drugs?</p> <p>15 A. Can you I guess explain -- can you</p> <p>16 restate that?</p> <p>17 Q. I don't think I can.</p> <p>18 A. Can you repeat that? Yeah. Prior to</p> <p>19 getting the notice to not destroy documents, did you</p> <p>20 take any evidence to consciously maintain documents</p> <p>21 that related to Medicaid payment for drugs.</p> <p>22 MS. MARTINEZ: Objection, form.</p>
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<p>1 documents when you moved jobs; is that right?</p> <p>2 MS. MARTINEZ: Objection, form.</p> <p>3 A. I didn't keep all of those documents. I</p> <p>4 got rid of a lot of those documents when I moved.</p> <p>5 Q. And when you say you got rid of, what do</p> <p>6 you mean by that?</p> <p>7 A. I mean, just deleted them off my hard</p> <p>8 drive because I didn't need the information, didn't</p> <p>9 need the information any longer.</p> <p>10 Q. Are you familiar with something called a</p> <p>11 document hold notice?</p> <p>12 MS. MARTINEZ: Objection to form.</p> <p>13 A. Can you explain that?</p> <p>14 Q. A notice for you to retain any files you</p> <p>15 may have related to a specific subject.</p> <p>16 A. Yes.</p> <p>17 Q. Have you ever received a document hold</p> <p>18 notice during your work at CMS?</p> <p>19 A. Yes.</p> <p>20 Q. Tell me about that. When did you get it</p> <p>21 and what did it cover?</p> <p>22 A. I can't remember the date on it, but it</p>	<p>1 A. Medicaid payment for drugs is kind of</p> <p>2 broad. So are you saying state plan amendments? I</p> <p>3 mean --</p> <p>4 Q. In your view what all would fall in the</p> <p>5 category of Medicaid payment for drugs, other than</p> <p>6 state plan amendments obviously that you indicated.</p> <p>7 A. You're asking me that?</p> <p>8 Q. Yes.</p> <p>9 A. Okay. I don't know. We have -- any kind</p> <p>10 of correspondence that maybe I replied to. So --</p> <p>11 Q. Did you make any efforts to retain any</p> <p>12 documents relating to state plan amendments prior to</p> <p>13 getting the hold notice?</p> <p>14 A. Well, the notice that -- I was in my new</p> <p>15 area so I didn't have the state plan amendment</p> <p>16 information with me.</p> <p>17 Q. Okay. Prior to getting the litigation</p> <p>18 hold notice and back during the time you were</p> <p>19 working on state plan amendment stuff --</p> <p>20 A. Okay.</p> <p>21 Q. -- did you make any conscious efforts to</p> <p>22 retain any of those documents?</p>

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<p style="text-align: right;">Page 94</p> <p>1 MS. MARTINEZ: Objection, form.</p> <p>2 A. I retained the documents.</p> <p>3 Q. All of them?</p> <p>4 A. I can't say all of them. What was</p> <p>5 pertinent to what I was working on at that time.</p> <p>6 Q. But if it didn't relate to what you were</p> <p>7 working on at the time, you didn't make an effort to</p> <p>8 keep them; is that right?</p> <p>9 MS. MARTINEZ: Objection, form.</p> <p>10 A. I can't answer that.</p> <p>11 Q. Did you use e-mail?</p> <p>12 A. Yes.</p> <p>13 Q. When did you start using e-mail?</p> <p>14 A. I can't remember.</p> <p>15 Q. Was it during the time that you were</p> <p>16 working on state plan amendments and federal upper</p> <p>17 limits?</p> <p>18 A. Yes.</p> <p>19 Q. Did you have e-mail correspondence on</p> <p>20 those subjects with anyone?</p> <p>21 A. Yes.</p> <p>22 Q. Was that something that you did</p>	<p style="text-align: right;">Page 96</p> <p>1 Q. That and anything else dealing with</p> <p>2 payment of drugs.</p> <p>3 MS. MARTINEZ: Objection, form.</p> <p>4 A. Yes.</p> <p>5 Q. Is that something that you did regularly?</p> <p>6 A. When it was necessary.</p> <p>7 Q. Do you recall being asked to search for</p> <p>8 documents relating to drug pricing litigation on or</p> <p>9 around 2003?</p> <p>10 A. I wouldn't -- I can't remember</p> <p>11 specifically that time frame.</p> <p>12 Q. But you recall an effort being made to</p> <p>13 search for documents relating to drug pricing</p> <p>14 litigation; is that fair to say?</p> <p>15 A. Correct.</p> <p>16 Q. And what involvement did you have in that</p> <p>17 search?</p> <p>18 A. I just searched my folders to see if I</p> <p>19 had any information that was relevant to the</p> <p>20 request. And generally the request would come</p> <p>21 through Larry's division, through policy, and they</p> <p>22 would copy me to see if we had any documents. And</p>
<p style="text-align: right;">Page 95</p> <p>1 regularly?</p> <p>2 A. Yes.</p> <p>3 Q. And where are those e-mails today?</p> <p>4 MS. MARTINEZ: Objection, form.</p> <p>5 A. I don't know.</p> <p>6 Q. Did you take any efforts to keep any</p> <p>7 e-mails?</p> <p>8 MS. MARTINEZ: Objection, form.</p> <p>9 A. From that period?</p> <p>10 Q. Yes.</p> <p>11 A. I really -- I'm not sure.</p> <p>12 Q. Do you have a sense on your computer --</p> <p>13 what is the approximate date of the oldest e-mail</p> <p>14 that you have access to on your computer?</p> <p>15 A. I have no idea.</p> <p>16 Q. Did you correspond by e-mail with people</p> <p>17 who administered the state Medicaid programs?</p> <p>18 A. Yes.</p> <p>19 Q. Relating to the way in which they paid</p> <p>20 for drugs? Is that a topic you e-mailed them about?</p> <p>21 A. Are you saying relating to state plan</p> <p>22 amendments?</p>	<p style="text-align: right;">Page 97</p> <p>1 if I did I would share them back with the policy</p> <p>2 folks and they would submit the document request.</p> <p>3 Q. Did you have any documents?</p> <p>4 A. I may have.</p> <p>5 Q. You don't recall?</p> <p>6 A. I don't recall.</p> <p>7 Q. Did you search your hard drive in your</p> <p>8 computer for documents that may have been responsive</p> <p>9 to the document requests?</p> <p>10 A. I may have.</p> <p>11 MR. TORBORG: Okay. We'll mark this as</p> <p>12 our next exhibit. I think I have ten copies of</p> <p>13 these, of the newly marked exhibits. I'll let you</p> <p>14 all fight about who gets the copies and who has to</p> <p>15 share.</p> <p>16 (Exhibit Abbott 453 was</p> <p>17 marked for</p> <p>18 identification.)</p> <p>19 MS. MARTINEZ: There's only four on the</p> <p>20 plaintiff's side. Could we have one more on the</p> <p>21 plaintiff's side? Thanks.</p> <p>22 MR. TORBORG: Now, when you say</p>

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<p>1 plaintiff's side, what do you mean?</p> <p>2 MS. MARTINEZ: What I mean --</p> <p>3 MR. TORBORG: That was a joke.</p> <p>4 MR. WINGET-HERNANDEZ: What are we</p> <p>5 calling this?</p> <p>6 MR. TORBORG: Abbott Exhibit 453. For</p> <p>7 the record, what I've marked as Abbott Exhibit 453</p> <p>8 bears the Bates numbers VAC MDL 86162 through 75.</p> <p>9 BY MR. TORBORG:</p> <p>10 Q. And Ms. Gaston, for purposes of my</p> <p>11 questioning here today if I ask you to flip to a</p> <p>12 Bates number or a reference number or some number,</p> <p>13 I'll be referring to the number that's printed on</p> <p>14 the bottom right corner of the document.</p> <p>15 A. Okay.</p> <p>16 Q. Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Okay? First I'd like you to review the</p> <p>19 entirety of this document and tell me whether or not</p> <p>20 you recall it.</p> <p>21 A. Did you say do I recall it?</p> <p>22 Q. Yes.</p>	<p>1 HCFA/MB?</p> <p>2 A. Yes.</p> <p>3 Q. Does that mean HCFA Medicaid Bureau?</p> <p>4 A. Correct.</p> <p>5 Q. And was there anyone else from the HCFA</p> <p>6 Medicaid Bureau in attendance?</p> <p>7 A. Larry Reed.</p> <p>8 MS. MARTINEZ: Objection, form. Is your</p> <p>9 question whether she recalls or is your question for</p> <p>10 her to read the document?</p> <p>11 MR. TORBORG: Read the document.</p> <p>12 A. Yeah. I'm reading the document. And</p> <p>13 from what I can see here, Larry Reed.</p> <p>14 Q. Are there any other names on this list</p> <p>15 that were on the Medicaid side of CMS?</p> <p>16 A. I can't say because I don't know what OBI</p> <p>17 or -- you know, but for my purposes I recognize</p> <p>18 Medicaid Bureau. I don't know what the WBB is.</p> <p>19 Q. If we go through the document a bit, on</p> <p>20 the next page, 164, it says "the false AWP</p> <p>21 multibillion dollar machine." Do you see that?</p> <p>22 A. Yes.</p>
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<p>1 A. (Reading.) I don't specifically recall</p> <p>2 it. It may look familiar, but -- because of the</p> <p>3 names on the front it shows that there was a meeting</p> <p>4 and I attended the meeting. So there could be a</p> <p>5 recollection, but I don't have much of a</p> <p>6 recollection at all.</p> <p>7 Q. You don't have much of a recollection of</p> <p>8 the meeting or the document?</p> <p>9 A. Either.</p> <p>10 Q. Okay. If I could ask you to go to the</p> <p>11 second page of the document, Bates ending 163, this</p> <p>12 appears to be an a sign-in sheet titled Ven-A-Care</p> <p>13 meeting, dated 9/14/95. Do you see that?</p> <p>14 A. Yes, I do.</p> <p>15 Q. And is your name listed on this document?</p> <p>16 A. Yes.</p> <p>17 Q. And you're listed next to number 16,</p> <p>18 right?</p> <p>19 A. Correct.</p> <p>20 Q. Is that your handwriting?</p> <p>21 A. Yes, it is.</p> <p>22 Q. And then under affiliation you wrote</p>	<p>1 Q. The next page is titled "manufacturer's</p> <p>2 false AWP's versus provider's true cost," do you see</p> <p>3 that?</p> <p>4 A. Yes.</p> <p>5 Q. And the next page, "manufacturers are</p> <p>6 also wholesalers - use false AWP's to promote drug</p> <p>7 sales to providers," do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. The next page, "HCFA defrauded into</p> <p>10 directing DMERCs to pay higher reimbursement based</p> <p>11 on false AWP," do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. We'll skip a couple pages to the Bates</p> <p>14 page ending 171. It says "Medicaid defrauded." Do</p> <p>15 you see that?</p> <p>16 A. Yes.</p> <p>17 Q. The first column is "AWP drives Medicaid</p> <p>18 reimbursement \$8 billion in 1993." "Medicaid</p> <p>19 victimized by false AWP's." "Medicaid victimized by</p> <p>20 Medicare paying false AWP's." Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. Do you recall this meeting, Ms. Gaston?</p>

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<p>1 A. No, I don't.</p> <p>2 Q. Do you recall anything at all about this</p> <p>3 meeting?</p> <p>4 A. No, I don't.</p> <p>5 Q. Do you recall at some point meeting with</p> <p>6 representatives from Ven-A-Care?</p> <p>7 A. Yes.</p> <p>8 Q. Tell me what you remember about those</p> <p>9 meetings.</p> <p>10 MS. MARTINEZ: Objection, form.</p> <p>11 A. I remember -- I remember them coming to</p> <p>12 CMS and discussing their issues. But I don't</p> <p>13 remember specifically anything more than that.</p> <p>14 Q. When you say to discuss their issues,</p> <p>15 what do you mean by that?</p> <p>16 A. From what I remember, they were concerned</p> <p>17 about pricing on certain drugs and Medicaid and</p> <p>18 Medicare reimbursing at higher levels than they felt</p> <p>19 were right.</p> <p>20 Q. And do you recall approximately when this</p> <p>21 meeting was?</p> <p>22 A. I don't recall, but it says on the paper</p>	<p>1 Q. Who was in attendance at that meeting, to</p> <p>2 your recollection?</p> <p>3 A. I don't know all the parties involved.</p> <p>4 Larry Reed was there. I don't know if Mary Salhus</p> <p>5 was there. And it may have been the administrator</p> <p>6 at that time. Other than that I don't remember</p> <p>7 anybody else.</p> <p>8 Q. Do you recall what was the nature of that</p> <p>9 meeting, what was discussed?</p> <p>10 A. I don't recall.</p> <p>11 Q. Do you recall where it was in D.C.?</p> <p>12 A. Specifically, no.</p> <p>13 Q. Do you recall the number of attendees</p> <p>14 generally?</p> <p>15 A. No.</p> <p>16 Q. Was it you and Mr. Reed and people from</p> <p>17 Ven-A-Care or was it larger than that?</p> <p>18 A. I don't recall.</p> <p>19 Q. Do you recall anything about the meeting</p> <p>20 at all?</p> <p>21 A. No.</p> <p>22 Q. That's because it's been some time; is</p>
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<p>1 '95.</p> <p>2 Q. So you do recall a little bit about the</p> <p>3 '95 meeting?</p> <p>4 MS. MARTINEZ: Objection to form.</p> <p>5 A. No. I don't remember this meeting.</p> <p>6 Q. But you recall Ven-A-Care coming to you</p> <p>7 in Baltimore to discuss their issues and concerns</p> <p>8 about pricing of certain drugs; is that right?</p> <p>9 MS. ALBEE: Objection, form.</p> <p>10 A. Coming to CMS.</p> <p>11 Q. Mm-hmm. And when I asked you when the</p> <p>12 meeting was you referred to this document, correct?</p> <p>13 A. No. I can't -- there could have been</p> <p>14 several meetings. I don't know if this is when they</p> <p>15 came to Baltimore.</p> <p>16 Q. You said there could have been several</p> <p>17 meetings. Do you recall more than one meeting with</p> <p>18 Ven-A-Care?</p> <p>19 A. There was another meeting in D.C.</p> <p>20 Q. Was that before or after the meeting in</p> <p>21 Baltimore?</p> <p>22 A. I don't know.</p>	<p>1 that correct?</p> <p>2 MS. MARTINEZ: Objection, form.</p> <p>3 A. Correct.</p> <p>4 Q. Your memory would have been better had I</p> <p>5 been able to ask you about this meeting five years</p> <p>6 ago; is that fair to say?</p> <p>7 MS. MARTINEZ: Objection, form.</p> <p>8 A. I can't say.</p> <p>9 Q. Do you recall any other meetings with</p> <p>10 Ven-A-Care?</p> <p>11 A. No.</p> <p>12 Q. Do you recall any other conversations</p> <p>13 with Ven-A-Care on the phone?</p> <p>14 A. There may have been. I don't recall.</p> <p>15 Q. You say that there may have been. Is</p> <p>16 that because you think that there were?</p> <p>17 MS. MARTINEZ: Objection, form.</p> <p>18 Q. You just don't recall the details of it?</p> <p>19 MS. MARTINEZ: Objection, form.</p> <p>20 A. Correct.</p> <p>21 Q. And who was in attendance on these phone</p> <p>22 calls?</p>

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<p>1 MS. ALBEE: Objection, form.</p> <p>2 MS. MARTINEZ: Objection, form.</p> <p>3 A. I don't remember the phone calls. There</p> <p>4 may have been, but I don't -- I don't know because I</p> <p>5 don't remember.</p> <p>6 Q. Did you take notes of the meetings with</p> <p>7 Ven-A-Care, either of the meetings with Ven-A-Care?</p> <p>8 A. I don't remember.</p> <p>9 Q. Would it have been your pattern and</p> <p>10 practice to take notes?</p> <p>11 MS. MARTINEZ: Objection, form.</p> <p>12 A. It just depends.</p> <p>13 Q. Depends on what?</p> <p>14 A. What meeting I was attending.</p> <p>15 Q. Would it have been your pattern and</p> <p>16 practice to take notes of a meeting of the type with</p> <p>17 Ven-A-Care?</p> <p>18 MS. ALBEE: Objection, form.</p> <p>19 MS. MARTINEZ: Objection, form.</p> <p>20 A. I can't say.</p> <p>21 Q. I'm going to ask you to go back to the</p> <p>22 Bates page ending 171. This is the slide for a page</p>	<p>1 A. Please.</p> <p>2 Q. -- because I can't either. Then the next</p> <p>3 column, VAC cost and then percentage difference? I</p> <p>4 think that's what it says, but I won't swear by it.</p> <p>5 MS. MARTINEZ: That's not legible.</p> <p>6 Q. Do you recall reviewing charts that</p> <p>7 compared AWP with Ven-A-Care's cost?</p> <p>8 A. No, I don't.</p> <p>9 MS. MARTINEZ: Objection, form.</p> <p>10 Q. But it appears as though these were</p> <p>11 presented in a meeting; is that fair to say?</p> <p>12 MS. MARTINEZ: Objection, form.</p> <p>13 A. I don't know.</p> <p>14 Q. Do you recall when you met with</p> <p>15 Ven-A-Care being surprised at what they were telling</p> <p>16 you?</p> <p>17 A. I don't really recall the meetings.</p> <p>18 Q. Did you have an understanding of why you</p> <p>19 would have been asked to attend a meeting with</p> <p>20 Ven-A-Care to discuss their concerns with drug</p> <p>21 pricing?</p> <p>22 MR. WINGET-HERNANDEZ: Objection, form.</p>
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<p>1 titled Medicaid defrauded. Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And in the middle column there, if you</p> <p>4 would look at that for a second and let me know if</p> <p>5 you have an understanding of what that chart is</p> <p>6 portraying.</p> <p>7 A. I can't see it. Do you have bigger</p> <p>8 print?</p> <p>9 Q. Not at this time.</p> <p>10 A. Okay.</p> <p>11 Q. Do you see that -- can you read the top?</p> <p>12 Medicaid drug cost? Can you read that?</p> <p>13 A. That's it. Yup.</p> <p>14 Q. Can you read the next column? NDC</p> <p>15 number?</p> <p>16 A. Barely. This is like an eye exam.</p> <p>17 Q. How about drug? Do you see that?</p> <p>18 A. Okay.</p> <p>19 Q. And then AWP, the next column?</p> <p>20 A. Okay.</p> <p>21 Q. I won't ask you to read the next</p> <p>22 column --</p>	<p>1 MS. MARTINEZ: Objection, form.</p> <p>2 A. As part of the division we would attend</p> <p>3 meetings just for educational purposes.</p> <p>4 Q. And what do you mean when you say</p> <p>5 educational purposes? What does that mean?</p> <p>6 A. Just to learn what's going on. And</p> <p>7 basically I think that's what my attendance here as</p> <p>8 part of the division -- just to, I guess, educate</p> <p>9 ourselves on what's happening.</p> <p>10 Q. And why would you need to be educated</p> <p>11 about what was happening?</p> <p>12 A. Because that's part of the job.</p> <p>13 Q. And was the idea to do something about</p> <p>14 the facts as presented by Ven-A-Care?</p> <p>15 MS. MARTINEZ: Objection, form.</p> <p>16 A. For me?</p> <p>17 Q. Yes.</p> <p>18 A. No.</p> <p>19 Q. Why would you need to know this</p> <p>20 information if you wouldn't use it?</p> <p>21 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>22 Q. Was it just to sort of know about it or</p>

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<p>1 was there a plan that you would do something about 2 it?</p> <p>3 MR. WINGET-HERNANDEZ: Same objection. 4 MS. MARTINEZ: Objection to form.</p> <p>5 A. I can't say. Just to educate myself. 6 Q. Education just for education's sake? 7 MS. MARTINEZ: Objection, form.</p> <p>8 Q. I'm trying to figure out why you were at 9 the meeting, why you're educating yourself about 10 these issues. Was it just to satisfy your -- 11 A. Because my supervisor probably asked me 12 to go to meeting. 13 Q. And do you have an understanding of why 14 you would be asked to go to meeting? 15 MR. WINGET-HERNANDEZ: Objection, form. 16 A. To learn more about the program. 17 Q. And then to do something about what you 18 learned; is that right? 19 MR. WINGET-HERNANDEZ: Objection to form 20 23450 objection, form. 21 MS. MARTINEZ: Objection, form. 22 A. No.</p>	<p>1 MS. ALBEE: Objection to form. 2 A. No. 3 Q. Do you recall any discussion or 4 consideration of doing anything about the facts as 5 presented by Ven-A-Care? 6 MS. MARTINEZ: Objection, form. 7 A. No. 8 Q. Did you make any efforts to inform your 9 colleagues in the state Medicaid programs about the 10 information presented by Ven-A-Care? 11 MS. MARTINEZ: Objection, form. 12 A. No. 13 Q. Why not? 14 A. Why not? Can you explain? 15 Q. Well, isn't one of HCFA's rules to help 16 educate states regarding pharmacy issues? 17 MS. MARTINEZ: Objection, form. 18 A. This was a litigation case. 19 Q. So is it your understanding that you were 20 in attendance at these meetings with Ven-A-Care in 21 connection with a litigation case? 22 MS. MARTINEZ: Objection, form.</p>
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<p>1 Q. So it was just to learn, it wasn't to 2 give you any knowledge base to do something; is that 3 your testimony? 4 MR. WINGET-HERNANDEZ: Objection, form. 5 MS. MARTINEZ: Objection, form. 6 A. To do something on this case? 7 Q. To do something about this situation as 8 presented by Ven-A-Care? 9 MS. MARTINEZ: Objection, form. 10 A. No. 11 Q. So what was the answer no to? My 12 question of was it just for curiosity's sake? Is 13 that what the answer no was to? 14 A. It wasn't for curiosity. 15 Q. It was to learn information so that you 16 would do something with the information you learned; 17 is that correct? 18 MS. MARTINEZ: Objection, form. 19 A. It was to educate myself. 20 Q. Do you recall taking any action in 21 response to the information presented by Ven-A-Care? 22 MS. MARTINEZ: Objection, form.</p>	<p>1 A. A potential litigation case, yes. 2 Q. Did you ever discuss with Mr. Reed or 3 anyone else what the Medicaid Bureau might do with 4 this information to save money for the government? 5 A. I can't say that. I don't know. 6 Q. Do you recall ever contacting 7 manufacturers to discuss the concerns raised by 8 Ven-A-Care on drug pricing issues? 9 MS. MARTINEZ: Objection, form. 10 A. No. 11 Q. Do you recall any discussion or 12 consideration within the Medicaid Bureau to contact 13 manufacturers about those issues? 14 MS. MARTINEZ: Objection, form. 15 A. No. 16 Q. Were you given any instructions not to 17 contact manufacturers about those issues? 18 MS. MARTINEZ: Objection, form. 19 A. I don't recall. 20 Q. If I can ask you to take out Exhibit 24 21 from the binders. For the record, this is a 22 document dated October 2nd 1996 addressed to Mr.</p>

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<p style="text-align: right;">Page 114</p> <p>1 Vladek from Zack Bentley and Mark Jones. I ask you 2 to take a look at that first, Ms. Gaston, and then 3 I'll have some questions for you. 4 A. (Reading.) I'm sorry. I'm looking at 5 the wrong thing. 6 Q. Exhibit 24. 7 A. Oh, I'm looking at -- yeah. Okay. 8 MS. MARTINEZ: It's upside-down. Here. 9 Do you want to use my book? Because my book is not 10 upside-down. There's a problem with that exhibit. 11 MR. TORBORG: There's what? 12 MS. MARTINEZ: There's a problem. It's 13 upside-down in my book so I'm giving her mine. Let 14 me see if I can follow this one that's backwards. I 15 can follow it backwards. 16 BY MR. TORBORG: 17 Q. Again, my first question, Ms. Gaston, is 18 whether or not you recall this document. 19 A. No, I don't. 20 Q. At the top of the first page there's a 21 handwritten notation. Do you see that? 22 A. Yes.</p>	<p style="text-align: right;">Page 116</p> <p>1 A. No, I don't recall. 2 Q. Is that because it's been some time that 3 you may have had those contacts? 4 MS. MARTINEZ: Objection, form. 5 A. It could be. 6 Q. The second paragraph refers to two 7 volumes of exhibits that "substantiate and support 8 the fact that Medicare and Medicaid programs are 9 continuing to make excessive reimbursements to 10 providers for infusion and inhalation 11 pharmaceuticals. These reimbursements are many 12 multiples over and above the amount that the 13 programs ever intended to pay." 14 Do you recall having a set of two volumes 15 of exhibits that had been prepared by Ven-A-Care? 16 MS. MARTINEZ: Objection, form. 17 A. I don't recall. 18 Q. Do you recall ever getting pricing 19 catalogs, pricing information from Ven-A-Care in the 20 form of pricing catalogs? 21 A. I don't recall. 22 Q. I'd like to ask you to go to the next</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. It appears to say BO something backlash 2 MB. Do you know whose handwriting that is? 3 A. No, I don't. 4 Q. Do you know what MB stands for within 5 HCFA? 6 MR. WINGET-HERNANDEZ: Objection, form. 7 Q. What is your understanding of the term? 8 When you see MB there what does it mean to you? 9 A. I could guess that it's Medicaid Bureau. 10 Q. Let me direct you to the first paragraph 11 of the letter. It says "Ven-A-Care of the Florida 12 Keys Inc. has attempted for more than seven years to 13 assist the Health Care Financing Administration and 14 the state Medicaid programs in limiting infusion and 15 inhalation pharmaceutical reimbursements to the 16 reasonable levels contemplated by the enabling 17 legislation." And this is dated October 2nd 1996. 18 Do you recall any efforts, any contacts, 19 with Ven-A-Care starting in the early 1990s or late 20 1980s, regarding the subject matter that I just 21 read? 22 MS. MARTINEZ: Objection, form.</p>	<p style="text-align: right;">Page 117</p> <p>1 page. I'm going to read in a paragraph that starts 2 after the indentation there. "Over a year ago." 3 Are you with me? 4 A. Yes. 5 Q. Ven-A-Care wrote "Over a year ago we 6 traveled to the HCFA in Baltimore and met with 7 various representatives of your agency and made a 8 detailed presentation regarding these excessive 9 reimbursements and their impact on the health care 10 delivery system. Unfortunately for the Medicare and 11 Medicaid programs as well as the American public to 12 date, no meaningful action has been either proposed 13 or implemented by your agency to deal with these 14 issues. We find this fact not only disconcerting 15 but potentially the source of a major embarrassment 16 to both your agency and to the administration." Do 17 you see that? 18 A. Yes, I do. 19 MS. MARTINEZ: Objection, form. 20 Q. Do you recall any action that CMS, 21 including the Medicaid Bureau, took to respond to 22 information that Ven-A-Care presented at the</p>

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<p style="text-align: right;">Page 118</p> <p>1 Baltimore meeting in 1995?</p> <p>2 MS. ALBEE: Objection, form.</p> <p>3 A. No.</p> <p>4 Q. So as far as you know, Ven-A-Care was</p> <p>5 correct that no meaningful action had been either</p> <p>6 proposed or implemented by your agency to deal with</p> <p>7 these issues?</p> <p>8 MS. MARTINEZ: Objection, form.</p> <p>9 A. I can't say that.</p> <p>10 Q. But you as you sit here today don't know</p> <p>11 of any meaningful action that had been taken?</p> <p>12 A. I personally don't know, but that doesn't</p> <p>13 mean that it didn't occur.</p> <p>14 Q. Sure. And I'm just asking for your</p> <p>15 personal knowledge as one of the two Medicaid</p> <p>16 officials that was at the meeting?</p> <p>17 MS. MARTINEZ: Objection, form.</p> <p>18 Q. Do you recall discussing the possibility</p> <p>19 of establishing federal upper limits for specific</p> <p>20 drugs that Ven-A-Care had identified there being a</p> <p>21 large difference between AWP and their cost?</p> <p>22 MS. MARTINEZ: Objection, form.</p>	<p style="text-align: right;">Page 120</p> <p>1 exploiting their ability" --</p> <p>2 A. I'm sorry. Where are you.</p> <p>3 Q. I'm at page 483?</p> <p>4 MS. MARTINEZ: It's page 5 of the letter</p> <p>5 and he's referring to the Bates label at the bottom</p> <p>6 that says 483.</p> <p>7 THE WITNESS: Thank you. Okay.</p> <p>8 Q. The first full paragraph starts with "the</p> <p>9 drug manufacturers." Are you with me?</p> <p>10 A. Uh-huh.</p> <p>11 Q. Ven-A-Care wrote "The drug manufacturers</p> <p>12 are further exploiting their ability to falsify</p> <p>13 pricing information by using their falsifications of</p> <p>14 AWP as a marketing tool." Do you have an</p> <p>15 understanding of what Ven-A-Care is saying there?</p> <p>16 MS. MARTINEZ: Objection to form.</p> <p>17 MS. ALBEE: Objection to the form.</p> <p>18 A. You're asking me to interpret this?</p> <p>19 Q. I'm asking if you have any understanding</p> <p>20 of what they're getting at there?</p> <p>21 MS. MARTINEZ: Objection, form.</p> <p>22 A. No.</p>
<p style="text-align: right;">Page 119</p> <p>1 A. No, not on those specific drugs. No.</p> <p>2 Q. Do you know why not?</p> <p>3 MS. MARTINEZ: Objection, form.</p> <p>4 A. I don't recall that being discussed.</p> <p>5 Q. Regarding Ven-A-Care's comment that "We</p> <p>6 find this fact" -- the fact that no meaningful</p> <p>7 action had been taken -- "not only disconcerting,</p> <p>8 but potentially the source of a major embarrassment</p> <p>9 to both your agency and to the administration," do</p> <p>10 you recall that being a discussion within HCFA that</p> <p>11 the Medicare and Medicaid programs paying above</p> <p>12 acquisition cost could be a major source of</p> <p>13 impairment for HCFA?</p> <p>14 MS. MARTINEZ: Objection, form.</p> <p>15 A. Do I recall a specific comment or -- is</p> <p>16 that what you're saying?</p> <p>17 Q. Generally speaking do you recall that</p> <p>18 sentiment being expressed ever?</p> <p>19 A. No, I don't.</p> <p>20 Q. I'd like to ask you to go to 483. The</p> <p>21 first full paragraph in the middle of the page</p> <p>22 states "The drug manufacturers are further</p>	<p style="text-align: right;">Page 121</p> <p>1 Q. You have no understanding of what they're</p> <p>2 saying about --</p> <p>3 A. Are you asking me what I feel this is</p> <p>4 saying?</p> <p>5 Q. Yes. Your understanding as someone who</p> <p>6 might read this letter.</p> <p>7 MS. MARTINEZ: Objection, form.</p> <p>8 A. It's saying that they're falsifying their</p> <p>9 AWP, their pricing, as a marketing tool. So, I</p> <p>10 mean, I don't know what more --</p> <p>11 Q. Do you have an understanding of how</p> <p>12 pricing information could be used as a marketing</p> <p>13 tool?</p> <p>14 MS. MARTINEZ: Objection, form.</p> <p>15 Q. Do you understand that concept?</p> <p>16 MS. MARTINEZ: Objection, form.</p> <p>17 A. Are you saying for just general sales or</p> <p>18 are you talking about for Medicare and Medicaid for</p> <p>19 reimbursement?</p> <p>20 Q. Do you think I'm talking about general</p> <p>21 sales or do you think I'm talking about pharmacy</p> <p>22 issues?</p>

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<p>1 A. That's what I'm asking you for 2 clarification. 3 Q. The latter. My questions are focused 4 on -- 5 A. Medicaid. 6 Q. Medicaid pharmacy issues. Yes. 7 A. You want me to interpret what this 8 statement says -- 9 Q. I'm asking -- I'm trying to get your 10 understanding of what that sentence is. 11 MS. MARTINEZ: Objection, form. 12 A. I mean, I'm just interpreting this and it 13 could be completely wrong. But it sounds like 14 they're falsifying the AWP. If marketing -- if 15 they're talking about for Medicaid and Medicare, 16 it's for the reimbursement that's going to occur to 17 Medicare and Medicaid and that it's going to be a 18 higher reimbursement rate. 19 Q. And are you familiar with the phrase 20 "marketing the spread"? 21 A. I've heard of it. 22 Q. And how have you heard of it?</p>	<p>1 familiar with the term. I don't know when I learned 2 the term. I don't -- I don't have any dates for 3 that. I don't know when I learned that. 4 Q. Are you familiar with the concept? 5 A. I'm familiar with the concept. 6 Q. And do you know when you first learned of 7 the concept? 8 A. No. 9 Q. And is that because it's been some time 10 ago since you first learned about the concept? 11 A. I can't say. 12 Q. Because it's been so long ago; is that 13 right? 14 MS. MARTINEZ: Objection, form. 15 A. I guess. 16 Q. To put a fine point on it, you can't tell 17 me when you first learned of the concept that drug 18 manufacturers are marketing spread because it's been 19 so long ago you can't remember; is that right? 20 MS. MARTINEZ: Objection, form. 21 MS. ALBEE: Objection, form. 22 A. It could be, but it could also be that</p>
Page 123	Page 125
<p>1 A. We hear of it on the news. 2 Q. In connection with Medicaid pharmacy 3 issues? 4 A. I don't really get involved with that, so 5 it doesn't really mean much to me. 6 Q. Are you familiar with the concept of 7 allegations that a drug manufacturer would market 8 the difference between AWP and acquisition price to 9 their customers to induce them to purchase their 10 drugs? Is that a concept that you're familiar with? 11 A. Yes. 12 Q. When did you first learn about that 13 potential -- that that potentially was going on? 14 A. Oh. I don't know. You asked me if I was 15 familiar with the term, which I am. But -- 16 Q. But you're familiar with the concept, 17 correct? 18 A. Yes. 19 Q. And you don't recall when you first 20 learned about that potentially was going on; is that 21 right? 22 A. I'm talking about the term, though. I'm</p>	<p>1 it's so vague. It's not one particular thing that 2 occurred to put a date to. It's a concept that's 3 used. So it's hard to put a date on when you first 4 heard of the concept. 5 MR. TORBORG: I'm going to do a couple 6 more and then -- do you guys want to take lunch at 7 12:00 or 1:00? What do you guys want to do? What's 8 your preference. 9 MS. MARTINEZ: Let's ask the witness. Do 10 you prefer lunch at 12:00 or 1:00? Do you feel like 11 the boss for a moment? 12 MR. WINGET-HERNANDEZ: It really is 13 entirely up to you. You should do what you feel 14 comfortable doing. 15 THE WITNESS: So you have enough to go to 16 1:00? 17 MR. TORBORG: Oh, yes. I have enough to 18 go all day. 19 THE WITNESS: I mean, but is this a good 20 break time? 21 MR. WINGET-HERNANDEZ: Yes. If you want 22 to take a break it's a good time.</p>

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<p style="text-align: right;">Page 126</p> <p>1 MS. MARTINEZ: If you need a break you</p> <p>2 tell us and if you want to take lunch at 12:00 you</p> <p>3 tell us and if you want to take it at 1:00 you tell</p> <p>4 us.</p> <p>5 MR. TORBORG: We can take a break now and</p> <p>6 then talk about it if you'd like. Let's take a</p> <p>7 little break and then I'll make a decision.</p> <p>8 THE VIDEOGRAPHER: This is the end of</p> <p>9 tape 2. Off the record at 11:50.</p> <p>10 (Recess.)</p> <p>11 THE VIDEOGRAPHER: This is the beginning</p> <p>12 of tape 3 in the deposition of Ms. Gaston. On the</p> <p>13 record at 12:06.</p> <p>14 BY MR. TORBORG:</p> <p>15 Q. Welcome back, Ms. Gaston. I've asked you</p> <p>16 to get out Abbott Exhibit 163.</p> <p>17 MS. MARTINEZ: And your servant, Ani</p> <p>18 Martinez, is getting it for you.</p> <p>19 MR. TORBORG: Thank you, Ani.</p> <p>20 Q. For the record, Abbott 163 is a July 10th</p> <p>21 1997 letter addressed to Mr. Vladek from Zachary</p> <p>22 Bentley, T. Mark Jones and John Lockwood.</p>	<p style="text-align: right;">Page 128</p> <p>1 proposal did not survive the House Ways and Means</p> <p>2 markup session.</p> <p>3 "Additionally you should be aware that</p> <p>4 the Health Care Financing Administration failed to</p> <p>5 offer or propose any recommendations that would have</p> <p>6 addressed these abuses in the states' Medicaid</p> <p>7 programs." Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. And in the Medicaid Bureau of CMS,</p> <p>10 correct?</p> <p>11 A. Correct.</p> <p>12 Q. Then known as HCFA, correct?</p> <p>13 A. Correct.</p> <p>14 Q. And were you aware of any recommendations</p> <p>15 to address the issues raised by Ven-A-Care</p> <p>16 concerning drug pricing that would affect the state</p> <p>17 Medicaid programs?</p> <p>18 MS. MARTINEZ: Objection, form.</p> <p>19 A. I don't recall.</p> <p>20 Q. Do you recall any discussion of proposing</p> <p>21 any recommendations?</p> <p>22 A. I don't recall.</p>
<p style="text-align: right;">Page 127</p> <p>1 Ms. Gaston, if you would take a look at</p> <p>2 that document and let me know if you've seen it</p> <p>3 before.</p> <p>4 A. I don't recall.</p> <p>5 Q. Do you recall receiving any letters from</p> <p>6 Ven-A-Care or being copied on or receiving a copy</p> <p>7 of?</p> <p>8 A. I don't recall.</p> <p>9 Q. I take it you didn't have a file for</p> <p>10 correspondence from Ven-A-Care?</p> <p>11 A. I may have. I don't recall.</p> <p>12 Q. You just don't recall because it's been</p> <p>13 so long ago?</p> <p>14 MS. MARTINEZ: Objection, form.</p> <p>15 A. Yes.</p> <p>16 Q. I'd like to ask you to go to the second</p> <p>17 paragraph of Ven-A-Care's July 10th 1997 letter to</p> <p>18 Mr. Vladek. They wrote "We have been closely</p> <p>19 monitoring your agency's recommended legislation.</p> <p>20 No markup on drugs directed at remedying these</p> <p>21 abuses in the Medicare program. We have recently</p> <p>22 been advised by Congressman Stark's office that this</p>	<p style="text-align: right;">Page 129</p> <p>1 Q. Did you have individuals within the</p> <p>2 Medicaid Bureau who worked on proposed regulations</p> <p>3 or legislation?</p> <p>4 A. Yes.</p> <p>5 Q. Who were those people? Do you recall?</p> <p>6 A. Estelle Chisholm and Mike Keough.</p> <p>7 Q. Anyone else?</p> <p>8 A. That's all I remember.</p> <p>9 Q. Do you recall ever CMS proposing any</p> <p>10 legislation concerning how much state Medicaid</p> <p>11 programs would pay for drugs?</p> <p>12 MS. MARTINEZ: Objection, form.</p> <p>13 A. I don't recall.</p> <p>14 Q. I'd like to ask you to flip to the next</p> <p>15 page. Ven-A-Care wrote "It would appear that HCFA's</p> <p>16 vested attempt at a partial remedy has failed.</p> <p>17 Nevertheless, HCFA has a duty and an obligation to</p> <p>18 protect the integrity of the Medicare and states'</p> <p>19 Medicaid programs to ensure that these programs are</p> <p>20 'prudent purchasers' of health care goods and</p> <p>21 services."</p> <p>22 Do you agree with that, Ms. Gaston?</p>

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<p style="text-align: right;">Page 130</p> <p>1 MS. MARTINEZ: Objection, form.</p> <p>2 A. What are you asking me to believe to?</p> <p>3 Q. Do you believe that HCFA had a duty and</p> <p>4 obligation to protect the integrity of the Medicare</p> <p>5 and states' Medicaid programs?</p> <p>6 MS. MARTINEZ: Objection, form.</p> <p>7 A. Are you just asking me my opinion?</p> <p>8 Q. Yes.</p> <p>9 A. I would say yes.</p> <p>10 Q. And is it your understanding that Mr.</p> <p>11 Reed shared that view?</p> <p>12 A. I can't speak for him.</p> <p>13 Q. Ms. Gaston, what is your view on what</p> <p>14 HCFA's duty was when it came to the amount that</p> <p>15 state Medicaid programs should be paying for</p> <p>16 providers to dispense drugs to Medicaid</p> <p>17 beneficiaries?</p> <p>18 MS. ALBEE: Objection, form.</p> <p>19 MS. MARTINEZ: Objection to form.</p> <p>20 A. Can you repeat the question?</p> <p>21 MR. TORBORG: Would you repeat it?</p> <p>22 (Whereupon, the requested portion was</p>	<p style="text-align: right;">Page 132</p> <p>1 MR. TORBORG: Yeah. I had actually asked</p> <p>2 that that be done this morning, so we're working on</p> <p>3 it.</p> <p>4 MS. MARTINEZ: Okay.</p> <p>5 Q. For the record, Abbott Exhibit 56 is a</p> <p>6 January 5th 1998 letter from Ven-A-Care addressed to</p> <p>7 Janet Reno, June Gibbs-Brown and Donna Shalala. Ms.</p> <p>8 Gaston, I'd ask that you take a look at that</p> <p>9 document.</p> <p>10 A. (Reading.)</p> <p>11 Q. And let me know if you have ever seen</p> <p>12 that document before.</p> <p>13 A. I don't recall seeing this.</p> <p>14 Q. I'd like to ask you to go to page 4 of</p> <p>15 the letter has the Bates page ending 048.</p> <p>16 A. Okay.</p> <p>17 Q. The last paragraph -- let me read it into</p> <p>18 the record and then ask you some questions about it.</p> <p>19 Ven-A-Care wrote "Be advised that we continue to be</p> <p>20 appalled and shocked by recent and past public</p> <p>21 statements made by members of the executive branch</p> <p>22 that the grossly excessive payments made by the</p>
<p style="text-align: right;">Page 131</p> <p>1 read by the reporter.)</p> <p>2 A. Are you asking me what HCFA's duty -- I</p> <p>3 mean, what we did, we had state plan amendments that</p> <p>4 we reviewed and we worked with the states.</p> <p>5 Q. Anything else?</p> <p>6 A. Like what?</p> <p>7 Q. I mean, was it HCFA's obligation to</p> <p>8 enforce the federal regulations governing how much</p> <p>9 states could pay for drugs?</p> <p>10 A. HCFA had the federal regulations. And we</p> <p>11 worked with the states to assure this they were</p> <p>12 adhering to the federal regulations.</p> <p>13 Q. Was it HCFA's obligation to ensure that</p> <p>14 that was done?</p> <p>15 MS. MARTINEZ: Objection, form.</p> <p>16 A. I can't answer that.</p> <p>17 Q. I'm going to ask you to go to Abbott</p> <p>18 Exhibit 56. It would be a different orange binder.</p> <p>19 MS. MARTINEZ: In the future you know</p> <p>20 what would be awesome is that when you had an</p> <p>21 exhibit if you actually knew the volume -- because</p> <p>22 you've got almost like 20 volumes.</p>	<p style="text-align: right;">Page 133</p> <p>1 Medicare and states' Medicaid programs for the</p> <p>2 pharmaceuticals at issue are somehow legal waste and</p> <p>3 are the result of some kind of 'loophole.'" Do you</p> <p>4 see that?</p> <p>5 A. Yes.</p> <p>6 Q. Do you recall that sentiment being</p> <p>7 expressed in connection with Medicaid reimbursement</p> <p>8 of drugs?</p> <p>9 MS. MARTINEZ: Objection, drugs.</p> <p>10 A. I don't recall.</p> <p>11 Q. Do you recall the term "loophole" being</p> <p>12 used in connection state Medicaid reimbursement of</p> <p>13 drugs?</p> <p>14 MS. MARTINEZ: Objection, form.</p> <p>15 A. I can't say.</p> <p>16 Q. You can't say because it's been some</p> <p>17 time?</p> <p>18 A. I can't say because it's a word. A word</p> <p>19 can be used. I can't say.</p> <p>20 Q. Do you recall the terms legal waste or</p> <p>21 waste being used in connection with Medicare or</p> <p>22 Medicaid payment for drugs?</p>

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<p style="text-align: right;">Page 134</p> <p>1 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>2 MS. MARTINEZ: Objection, form.</p> <p>3 A. I can't say.</p> <p>4 Q. You can't say because it's been some time</p> <p>5 since the events on these issues transpired?</p> <p>6 MS. MARTINEZ: Objection.</p> <p>7 A. No. I can't say just because of the</p> <p>8 words. They're very general in nature and I can't</p> <p>9 say.</p> <p>10 Q. I'd like to ask you to flip one back, to</p> <p>11 Abbott Exhibit 55. This is a document titled</p> <p>12 "remarks by the President in radio address to the</p> <p>13 nation." It appears to be from the White House</p> <p>14 Office of the Press Secretary. I'd ask you to take</p> <p>15 a look at that and let me know if you're familiar</p> <p>16 with these remarks.</p> <p>17 A. (Reading.) I'm not familiar with this.</p> <p>18 Q. If I can direct you to the fourth</p> <p>19 paragraph, it starts with "but we must do more." Do</p> <p>20 you see that?</p> <p>21 A. Yes, I do.</p> <p>22 Q. Mr. Clinton stated "But we must do more.</p>	<p style="text-align: right;">Page 136</p> <p>1 system?</p> <p>2 MS. MARTINEZ: Objection, form.</p> <p>3 A. Are you asking if I've heard that term</p> <p>4 or --</p> <p>5 Q. Have you heard that sentiment expressed?</p> <p>6 A. No. I can't say.</p> <p>7 Q. With respect to the last sentence, "In</p> <p>8 fact some pay just one-tenth of the published</p> <p>9 price" -- do you see that?</p> <p>10 A. Yes, I see it.</p> <p>11 Q. Did you become aware of the fact that</p> <p>12 there were times that the average wholesale price</p> <p>13 could be ten times or more higher than what</p> <p>14 providers were paying to acquire drugs?</p> <p>15 MS. MARTINEZ: Objection, form.</p> <p>16 A. Are you asking me specifically if I'm</p> <p>17 aware of that?</p> <p>18 Q. Yeah. Did you become aware of that?</p> <p>19 MS. MARTINEZ: Objection, form.</p> <p>20 A. I couldn't say. It would depend on the</p> <p>21 situation.</p> <p>22 Q. And what do you mean by that, depend on</p>
<p style="text-align: right;">Page 135</p> <p>1 Sometimes the waste and abuses aren't even illegal;</p> <p>2 they're just embedded in the practices of the</p> <p>3 system. Last week the Department of Health and</p> <p>4 Human Services confirmed that our Medicare program</p> <p>5 has been systemically overpaying doctors and clinics</p> <p>6 for prescription drugs, overpayments that cost</p> <p>7 taxpayers hundreds of millions of dollars.</p> <p>8 "Such waste is simply unacceptable. Now,</p> <p>9 these overpayments occur because Medicare reimburses</p> <p>10 doctors according to the public average wholesale</p> <p>11 price, the so-called sticker price for drugs. Few</p> <p>12 doctors, however, actually pay the full sticker</p> <p>13 price. In fact some just pay one-tenth of the</p> <p>14 published price." Do you see that?</p> <p>15 A. Yes, I do.</p> <p>16 Q. Does that refresh your recollection at</p> <p>17 all about whether or not you've seen --</p> <p>18 A. No. It doesn't look familiar to me.</p> <p>19 Q. Do you recall any discussions at HCFA or</p> <p>20 with state representatives that basing payment on</p> <p>21 average wholesale price was something that was not</p> <p>22 illegal; it was just embedded in the practice of the</p>	<p style="text-align: right;">Page 137</p> <p>1 the situation?</p> <p>2 A. I mean, I wouldn't -- unless it was</p> <p>3 brought to my attention, I'm not aware of it.</p> <p>4 Q. But if there are documents that you</p> <p>5 reviewed -- you may have reviewed documents that</p> <p>6 would have expressed that information; is that</p> <p>7 right?</p> <p>8 A. No, not that I'm aware of.</p> <p>9 Q. You don't recall?</p> <p>10 A. No, I don't recall.</p> <p>11 Q. Okay. But you may have. You just don't</p> <p>12 recall because it's been some time. Is that fair to</p> <p>13 say?</p> <p>14 MS. MARTINEZ: Objection, form.</p> <p>15 A. I don't know.</p> <p>16 Q. Why don't you know?</p> <p>17 A. Because I don't know if that even</p> <p>18 occurred.</p> <p>19 Q. Because it's been some time; is that</p> <p>20 correct?</p> <p>21 A. Yes.</p> <p>22 Q. If you became aware of fraud in the</p>

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<p style="text-align: right;">Page 138</p> <p>1 Medicaid system are there steps that you're supposed 2 to take, Ms. Gaston? 3 MS. MARTINEZ: Objection, form. 4 A. Can you give me an example? 5 Q. Have you received training or any 6 guidance about what someone in your position is 7 supposed to do if they learn of fraud in the 8 Medicaid system? 9 A. I haven't received training. I know that 10 the regional office have offices that deal with 11 fraud and CMS has an office that deals with fraud. 12 Q. But are you aware of any guidance to you 13 about what you're supposed to do if you learn about 14 fraud in the Medicaid system? 15 A. No. 16 Q. Do you recall ever raising an issue 17 during your time at CMS about drug pricing being 18 fraudulent? 19 A. Can you be more specific? 20 Q. I'm asking a very broad question. 21 A. Just general? 22 Q. Yeah.</p>	<p style="text-align: right;">Page 140</p> <p>1 MR. TORBORG: I contend it's been 2 produced in the same Bates range. I'm not here to 3 make contentions about documents. I'm here to ask 4 questions of witnesses about documents. 5 MR. WINGET-HERNANDEZ: Well, okay. But 6 you have -- 7 MR. TORBORG: You can reserve your 8 objection if this gets made at trial. Otherwise 9 don't interrupt my questioning. 10 MR. WINGET-HERNANDEZ: You've marked a 11 document which you have attached the pages together 12 as though it's a single document when on its face it 13 shows that it's an eight page fax. The document has 14 eleven pages in it. I'm just asking you to clarify 15 that apparent mistake or confusion if you can. If 16 you can't then that's fine. 17 MR. TORBORG: I can't. I didn't produce 18 them. 19 MR. WINGET-HERNANDEZ: But did you attach 20 them? Apparently you did. 21 MS. MARTINEZ: Right. Are you saying 22 these --</p>
<p style="text-align: right;">Page 139</p> <p>1 A. I don't recall specifically. 2 Q. Do you recall anything generally? 3 A. No. 4 MR. TORBORG: Okay. I'd like to mark 5 this as our next exhibit. 6 (Exhibit Abbott 454 was 7 marked for 8 identification.) 9 BY MR. TORBORG: 10 Q. For the record, what I've marked as 11 Abbott Exhibit 454 bears the Bates numbers VAC MDL 12 64417 through 27. Ms. Gaston, I ask you to take a 13 look at that document and tell me whether or not you 14 recall it. 15 A. (Reading.) 16 Q. For the record, this is a fax cover sheet 17 dated January 22nd 1998 from Zack Bentley and Mark 18 Jones to Congressman Pete Stark attaching a letter 19 of the same date from Ven-A-Care to Congressman 20 Stark. 21 MR. WINGET-HERNANDEZ: David, do you 22 contend that this is all one document?</p>	<p style="text-align: right;">Page 141</p> <p>1 MR. TORBORG: I'm not making contentions 2 about documents. I'm asking the witness about 3 documents. You can reserve your objections on this 4 stuff. It's wasting time. 5 MR. WINGET-HERNANDEZ: Well, I object to 6 the attachment of this document to the deposition in 7 the form that it's been provided based upon the fact 8 that on the its face it shows it's supposed to be an 9 eight page document and it has more than eight pages 10 in it. That's my objection. 11 MS. MARTINEZ: Obviously the objection is 12 good for everybody on the plaintiff's side and the 13 United States has the same objection. 14 BY MR. TORBORG: 15 Q. Ms. Gaston, are you familiar with this 16 document? 17 A. No, I'm not. 18 Q. If I can ask you to go to the Bates page 19 ending 419, there's a re: line titled "Suggested 20 Course of Action for You to Encourage HCFA to Take 21 Concerning the 22 Drugs Identified in the OIG Report 22 Entitled 'Excessive Medicare Payments for</p>

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<p style="text-align: right;">Page 142</p> <p>1 Prescription Drugs." And it gives a number and a 2 date. 3 In the first paragraph, Ven-A-Care wrote 4 "As you may be aware, in September 1995 we met with 5 representatives from the OIG and HCFA in Baltimore 6 to discuss and present evidence of the fact that the 7 Medicare and states' Medicaid programs were 8 unwittingly making excessive reimbursements for 9 certain infusion, injectable and inhalation drugs." 10 That's the meeting we saw earlier that 11 looked like you attended; is that right? 12 MS. MARTINEZ: Object to form. 13 A. That meeting was in '95. 14 Q. It goes on, "During that meeting we were 15 shocked by certain statements made by certain HCFA 16 officials concerning their understanding that the 17 term 'AWP' had never been legislatively or 18 administratively defined by the federal government." 19 Ms. Gaston, does that refresh your 20 recollection at all regarding any conversation about 21 that subject that occurred in the Baltimore meeting 22 with Ven-A-Care in 1995?</p>	<p style="text-align: right;">Page 144</p> <p>1 don't mean to be rude, but what is it exactly that 2 you don't understand about the words average, 3 wholesale, and price and/or the words average 4 wholesale price put together as AWP?" Do you see 5 that? 6 A. Yes, I do. 7 MS. MARTINEZ: Objection, form. 8 Q. Do you recall there ever being any 9 discussion of any issue within HCFA about what the 10 term AWP meant? 11 MS. MARTINEZ: Objection, form. 12 A. Can you be more specific? Just what it 13 means? 14 Q. Yeah. 15 A. There may have been discussions. I don't 16 remember any specific discussions. 17 Q. Do you remember -- when you used the word 18 or the phrase "average wholesale price," what did 19 you understand it to mean? 20 MS. ALBEE: Objection, form. 21 A. Average wholesale price was a price that 22 we used along with the direct price or the WAC price</p>
<p style="text-align: right;">Page 143</p> <p>1 A. No. 2 Q. Do you recall that subject ever being 3 discussed within HCFA, the fact that AWP, that term, 4 had never been legislatively or administratively 5 defined? 6 A. I don't recall. 7 Q. You don't recall any discussions about 8 that issue? 9 A. I don't recall. 10 Q. And is that because it's been some time 11 since both the September 1995 meeting as well as 12 your time dealing with these issues? 13 MS. MARTINEZ: Objection, form. 14 A. It could be. 15 Q. If I could ask you to go to the next 16 page. Ven-A-Care wrote "We contacted an official at 17 the Bureau of Labor Statistics, Department of 18 Commerce, whose branch of government also uses the 19 words average wholesale price and the term AWP. 20 When we asked if the Commerce Department had ever 21 defined the words 'average wholesale price' or the 22 term 'AWP,' the official stated 'Mr. Bentley, I</p>	<p style="text-align: right;">Page 145</p> <p>1 for determining the FULs. It really wasn't our 2 place -- for me when I'm working on the FULs -- to 3 get into defining it. I'm looking at it for FULs 4 purposes. 5 Q. And where did you look to get average 6 wholesale prices? 7 MS. MARTINEZ: Objection, form. 8 A. The three prices the average wholesale 9 price, direct price and the wholesale acquisition 10 cost, was provided to us by the compendia sources. 11 Q. That would be Blue Book, Red Book and 12 Medi-Span? 13 A. Correct. 14 Q. And when you use the term average 15 wholesale price and when you saw it used by others 16 such as in state plans, that's what you understood 17 the term to mean; is that right? 18 MS. MARTINEZ: Objection, form. 19 A. You mean to mean -- not defining it, but 20 how I use it? 21 Q. Yeah. It meant what was in Blue Book, 22 Red Book and other compendia?</p>

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<p style="text-align: right;">Page 146</p> <p>1 A. It's a price that's provided in the 2 compendia. 3 Q. And that's what you understood the term 4 to mean; is that right? 5 MS. MARTINEZ: Objection, form. 6 A. I wasn't defining it. It's a price. 7 Q. I'm not asking you to define it. I'm 8 asking you to tell me what was your understanding of 9 what AWP meant. 10 MS. MARTINEZ: Objection, form. 11 A. It was a price that was submitted by the 12 manufacturers and -- just like direct price and 13 wholesale acquisition cost. 14 Q. And it was something that you found in 15 the compendia? 16 A. Correct. 17 MR. TORBORG: We'll mark this as our next 18 exhibit. 19 (Exhibit Abbott 455 was 20 marked for 21 identification.) 22 BY MR. TORBORG:</p>	<p style="text-align: right;">Page 148</p> <p>1 Q. Do you have a name you use for that 2 project that you and I can understand each other if 3 we talk about it later? 4 A. No. 5 Q. If I call it the DOJ AWP project will you 6 understand what I'm talking about? 7 A. You can call it that. That would be 8 fine. 9 Q. That's not a term you used, but it's a 10 term if I use it today you'll understand what I 11 mean? 12 A. That's fine. 13 Q. I'd ask you if you would go to the 14 second-to-last page in the document, Bates page 15 ending 284. It's a page titled "action item number 16 6." Then it also says "record of sign-offs." And I 17 see your name there. 18 A. Correct. 19 Q. Can you tell me what this document is and 20 what it's signifying? 21 A. My recollection, this is probably a cover 22 sheet to a control. And you sign off if -- I</p>
<p style="text-align: right;">Page 147</p> <p>1 Q. Ms. Gaston, what I've marked as Abbott 2 Exhibit 455 bears the Bates numbers HHD 101-1266 3 through 85. It appears to be a letter dated 4 September 27th 2001 from Janet Rehnquist, Inspector 5 General, to Thomas Scully, subject: OIG final 6 report, "Medicaid's use of revised average wholesale 7 prices." And then it attaches a copy of that 8 report, as well as some other documents I'll be 9 asking you about. 10 I ask you to take a look at that and let 11 me know if you're familiar with this document. 12 A. (Reading.) Okay. 13 Q. Ms. Gaston, do you recall this particular 14 OIG report? 15 A. It looks familiar. 16 Q. Do you recall an effort that the 17 Department of Justice made in connection with NAMFCU 18 to develop revised average wholesale pricing for 19 certain prescription drugs that occurred in the time 20 period of the late '90s and early 2000, 2001? 21 MS. MARTINEZ: Objection, form. 22 A. Yes.</p>	<p style="text-align: right;">Page 149</p> <p>1 guess -- to the response, I'm guessing. It could be 2 to the response to the OIG report. 3 Q. And does the fact that your name is 4 listed there under cleared by, or next to cleared 5 by -- what does that mean? 6 A. It means that I probably had some input 7 into the response. 8 Q. Into the response to the OIG report? 9 A. Correct. 10 Q. And other people are -- is the next one 11 Reed? 12 A. Correct. 13 Q. Any idea what the other ones are, based 14 on either your ability to read handwriting better 15 than me and your knowledge of who the people would 16 be? 17 A. I'm not sure of the next one. The other 18 one says PCPG, which is -- generally they do more 19 the administrative work. And OCD would be I would 20 say the center director's office. But I don't know 21 whose names they were. 22 Q. What is the center -- what does OCD --</p>

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<p style="text-align: right;">Page 150</p> <p>1 A. I would say OCD. I'm guessing. But I 2 would say that it would be the center director. So 3 it could be maybe up to the Medicaid directors. 4 Q. Medicaid directors within HCFA? 5 A. Within CMSO. And here again, I'm not 6 sure. Office center director. 7 Q. So that could be someone like Dennis 8 Smith maybe? 9 A. It could be. 10 Q. Do you know what the CMSO/FCHPG would be? 11 A. Family and Children's Health Programs 12 Group. 13 Q. Any idea -- 14 A. That's the group that Larry was under. 15 The policy area was under that group. 16 Q. Any idea who that name might be next to 17 it? 18 A. No. 19 Q. Do you recall attending the -- do you 20 recall that there were exit and entrance conferences 21 for various OIG reports? 22 A. Yes.</p>	<p style="text-align: right;">Page 152</p> <p>1 A. I don't recall. 2 Q. You indicated earlier that you believe 3 that the Bates page ending 1284 on Abbott Exhibit 4 455 may indicate you had some input into the 5 comments to the report; is that right? 6 A. Correct. 7 Q. Tell me about how that process works, how 8 comments are made, what review they undergo, that 9 practice. 10 A. The process? 11 Q. Yes. 12 A. If we receive an OIG report and we have 13 to review it and make comments on it, whoever it's 14 assigned to, we would do whatever research needed to 15 be performed and do a draft of our comments and then 16 give it to Larry Reed for him to review. And then a 17 final will be prepared and forwarded up through the 18 channels up to -- generally up to the center 19 director's office. 20 Q. And the center director's office would 21 be -- 22 A. Like a Dennis Smith.</p>
<p style="text-align: right;">Page 151</p> <p>1 Q. Do you recall ever attending those? 2 A. Yes. 3 (Exhibit Abbott 456 was 4 marked for 5 identification.) 6 BY MR. TORBORG: 7 Q. For the record, what I've marked as 8 Abbott Exhibit 456 bears the Bates number HHD 9 042-0164. Do you have an understanding of what this 10 document is, Ms. Gaston? 11 A. It looks like a meeting participant list. 12 Q. And you're familiar with these type of -- 13 this type of document in your work? 14 A. Yes. 15 Q. And is your name listed there third from 16 the bottom? 17 A. Yes. 18 Q. Is that your handwriting? 19 A. Yes, it is. 20 Q. Do you recall attending the exit 21 conference for the OIG project Medicaid's use of 22 revised AWP?</p>	<p style="text-align: right;">Page 153</p> <p>1 Q. -- a Dennis Smith type? 2 When did Dennis Smith start at the 3 Medicaid Bureau or at CMSO? 4 A. I don't recall. 5 Q. But you recall the comments would 6 initially be drafted by someone at your level and 7 then they would be forwarded up to Mr. Reed? 8 A. Correct. 9 Q. You don't recall Mr. Reed doing a first 10 draft of any comments; is that fair to say? 11 MS. MARTINEZ: Objection to form. 12 Q. That wasn't the practice? 13 MS. MARTINEZ: Objection to form. 14 A. That wasn't the practice. 15 Q. Then Mr. Reed would review it and approve 16 it; is that right? And then he would send it on to 17 the center director's office? 18 A. I think there were other offices that we 19 had to -- the group. And sometimes I guess it 20 would -- I'm not sure because my recollection isn't 21 that clear. But generally if something filters up 22 to the center director's office, it has to go to the</p>

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<p>1 next channel, which would be the group director. 2 And then from the group director up to the center 3 director's office. 4 Q. So is it fair to say a lot of steps go 5 into the process of the comments that CMS provides 6 to an OIG report? 7 A. Correct. 8 Q. A lot of review is done for the accuracy 9 and appropriateness of the comments; is that fair to 10 say? 11 MR. WINGET-HERNANDEZ: Objection, form. 12 MS. MARTINEZ: Objection, form. 13 A. I couldn't say. 14 Q. But in your view it was something that 15 CMS took pretty seriously? 16 MR. WINGET-HERNANDEZ: Objection, form. 17 MS. MARTINEZ: Objection, form. 18 A. I can only speak for myself. 19 Q. Okay. 20 A. I take it seriously. 21 Q. Now, if we look at the comments -- and 22 let me make sure I get this straight. The process</p>	<p>1 A. Yes. 2 Q. So did he work underneath Dennis Smith? 3 A. No. He was the deputy to the 4 administrator. 5 Q. So he was above Dennis Smith? 6 A. Correct. 7 Q. Did you ever meet with Mr. King-Shaw? 8 A. No. 9 Q. And here he's providing CMS's comments to 10 this report; is that right? 11 A. That's what it appears to be. 12 Q. And you're -- let me ask you this. Do 13 you recall drafting comments, at least a draft 14 version of comments, to this particular OIG report? 15 A. I don't remember. 16 Q. But you believe that you may have had 17 input into it? 18 A. I may have. 19 Q. Okay. Why don't with you look at this a 20 second. Mr. King-Shaw's memo states "Thank you for 21 the opportunity to review and comment on the 22 above-referenced draft report regarding state</p>
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<p>1 that you were talking about, that relates to the 2 comments that were given to a draft report? That's 3 when you first get the opportunity to do comments, 4 right? You get a copy of OIG's draft report, you 5 make comments and OIG may modify its report based on 6 your comments? 7 A. Correct. 8 Q. Right? If we go to Bates page 1281 of 9 Abbott Exhibit 455, can you tell us what this 10 document is? This and the next page. 11 A. It looks like a letter to the OIG from 12 our -- is it deputy administrator? -- with the draft 13 comments. 14 Q. When you say draft comments, what do you 15 mean by that? You mean comments on a draft report? 16 A. Correct. 17 Q. And do you remember a man by the name of 18 Reuben King-Shaw Jr.? 19 A. Yes. 20 Q. He was a deputy administrator? 21 A. Correct. 22 Q. Chief operating officer?</p>	<p>1 Medicaid's use of revised average wholesale prices 2 (AWPs) for certain prescription drugs. 3 Investigative findings by the Department of Justice 4 and the National Association of Medicaid Fraud 5 Control Units (NAMFCU) reveal that some drug 6 manufacturers were reporting inflated average 7 manufacturer prices for certain drug products. 8 "As a result, actual wholesale pricing 9 data were collected for approximately 400 national 10 drug codes representing 51 drugs." And you recall 11 that project, right? 12 MS. MARTINEZ: Objection, form. 13 A. It looks familiar, but I don't recall -- 14 I don't recall the details. 15 Q. The second paragraph states "While there 16 were no recommendations noted in this report, the 17 Centers for Medicare and Medicaid Services agreed 18 with OIG's conclusion that reliance on the reported 19 AWP's by drug manufacturers as a basis for drug 20 reimbursement is problematic." Do you see that? 21 A. Yes, I do. 22 Q. And that something that you agreed with</p>

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<p style="text-align: right;">Page 158</p> <p>1 at the time?</p> <p>2 A. I can't remember.</p> <p>3 Q. The next sentence says "Additionally, we</p> <p>4 acknowledge OIG's comments and earlier reports</p> <p>5 regarding the shortcomings of using AWP's as a basis</p> <p>6 for reimbursement and will continue to look for</p> <p>7 administrative and legislative solutions to this</p> <p>8 problem." Do you recall efforts that the Medicaid</p> <p>9 Bureau or CMSO took in looking for administrative</p> <p>10 and legislative solutions to this problem?</p> <p>11 A. I don't remember.</p> <p>12 Q. Let's go to the next page, if you would.</p> <p>13 The paragraph states "The OIG concludes that because</p> <p>14 most states base their reimbursement for drugs on</p> <p>15 AWP's, inflated AWP's have 'caused Medicaid to overpay</p> <p>16 for these products.'" And it says, paren, "See</p> <p>17 pages little I conclusion and 9 first paragraph."</p> <p>18 You understand that that's referring to language</p> <p>19 that was in a draft report?</p> <p>20 A. If you say so.</p> <p>21 Q. Well, I'm just asking your interpretation</p> <p>22 of that. That's what it looks like to you? This</p>	<p style="text-align: right;">Page 160</p> <p>1 Q. Did I read it correctly?</p> <p>2 A. Yes.</p> <p>3 Q. Do you recall being involved in drafting</p> <p>4 this language?</p> <p>5 A. I don't recall.</p> <p>6 Q. Do you have an understanding of what it's</p> <p>7 saying?</p> <p>8 A. Yes.</p> <p>9 Q. Can you tell me in your words what you</p> <p>10 understand it to be saying?</p> <p>11 A. That the comments are saying they have a</p> <p>12 concern over the statement saying overpaid and they</p> <p>13 wanted it deleted from the comments, from that part</p> <p>14 of the OIG report.</p> <p>15 Q. And why did CMS have a concern with use</p> <p>16 of the term overpayment or overpay?</p> <p>17 MS. ALBEE: Objection, form.</p> <p>18 A. Yeah. I can't speak for them. I don't</p> <p>19 know if this was language I prepared or who</p> <p>20 prepared. So I can't speak to it.</p> <p>21 Q. As you read it here today what do you</p> <p>22 take it to mean?</p>
<p style="text-align: right;">Page 159</p> <p>1 memo --</p> <p>2 A. Yeah. It appears that's what it's</p> <p>3 referencing.</p> <p>4 Q. And let's go back to the first paragraph</p> <p>5 of the letter. It says "Thank you for the</p> <p>6 opportunity to review and comment on the above-</p> <p>7 referenced draft." Do you see that?</p> <p>8 A. Okay.</p> <p>9 Q. Does that suggest to you the language</p> <p>10 here that we just talked about was contained in a</p> <p>11 draft OIG report?</p> <p>12 A. Yes.</p> <p>13 Q. And then it continues on "Since the</p> <p>14 regulations and relevant state plans authorize</p> <p>15 payment for drugs based on AWP's, regardless of</p> <p>16 whether those prices are inflated, we have concerns</p> <p>17 with the statement that states and Medicaid have</p> <p>18 'overpaid for drugs. We therefore recommend that</p> <p>19 the sentence on pages little I, penultimate</p> <p>20 paragraph, second sentence, and 9, first paragraph,</p> <p>21 second sentence, be deleted." Do you see that?</p> <p>22 A. I do.</p>	<p style="text-align: right;">Page 161</p> <p>1 A. That they have an objection to the word</p> <p>2 overpaid and they don't want that in the report.</p> <p>3 Q. Because the regulations in the relevant</p> <p>4 state plans authorize payment for drugs based upon</p> <p>5 published average wholesale prices, correct?</p> <p>6 MS. ALBEE: Objection, form.</p> <p>7 MS. MARTINEZ: Objection, form.</p> <p>8 Q. That's when it says, right? I'm not</p> <p>9 making that up.</p> <p>10 MS. MARTINEZ: No. That's not what it</p> <p>11 says.</p> <p>12 A. Yeah. The state plans say --</p> <p>13 MS. MARTINEZ: I just want to say for the</p> <p>14 record --</p> <p>15 MR. TORBORG: No.</p> <p>16 MS. MARTINEZ: You misread it. The word</p> <p>17 "published" is not in there. The word "published"</p> <p>18 is not in there. And you read it into it.</p> <p>19 MR. TORBORG: Okay.</p> <p>20 BY MR. TORBORG:</p> <p>21 Q. When you saw the words AWP's there, you</p> <p>22 thought it referred to published AWP's, did you not?</p>

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<p style="text-align: right;">Page 162</p> <p>1 A. Yes.</p> <p>2 Q. And it says that "The regulations and</p> <p>3 relevant state plans authorize payment for drugs</p> <p>4 based on AWP's regardless of whether those prices are</p> <p>5 inflated." Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. And what did you understand the term</p> <p>8 "inflated" to mean?</p> <p>9 A. Inflated? Higher than what they should</p> <p>10 be.</p> <p>11 Q. And this particular inflation -- this</p> <p>12 particular project relates to some 400 national drug</p> <p>13 codes that were part of the DOJ AWP effort, correct?</p> <p>14 MS. MARTINEZ: Objection, form.</p> <p>15 A. Yes.</p> <p>16 Q. And this is saying, is it not, that even</p> <p>17 though prices for these NDCs may be inflated, state</p> <p>18 Medicaid programs are not "overpaying" for these</p> <p>19 drugs because the regulations and state plans</p> <p>20 authorize payments for these drugs based upon the</p> <p>21 inflated AWP's for those drugs, is it not?</p> <p>22 MS. MARTINEZ: Objection, form.</p>	<p style="text-align: right;">Page 164</p> <p>1 been so long ago that --</p> <p>2 Q. I'm asking for your interpretation today.</p> <p>3 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>4 A. I have to ask you to read your question</p> <p>5 again.</p> <p>6 Q. This is saying, is it not, that even</p> <p>7 though prices for these NDCs may be inflated, state</p> <p>8 Medicaid programs are not "overpaying" for these</p> <p>9 drugs because the regulations and state plans</p> <p>10 authorize payments for these drugs based upon the</p> <p>11 inflated AWP's for those drugs, is it not?</p> <p>12 MS. MARTINEZ: Objection, form.</p> <p>13 MS. ALBEE: Objection, form.</p> <p>14 A. I don't think they were saying they were</p> <p>15 overpaying. I think they want that word "overpaid"</p> <p>16 in there to imply that. But I don't think it's</p> <p>17 coming out and saying that they weren't overpaying.</p> <p>18 Q. Why is your objection to the word</p> <p>19 "overpaid"?</p> <p>20 A. I don't know. They're saying it in here</p> <p>21 they want it removed. So I'm just repeating what's</p> <p>22 said in the document.</p>
<p style="text-align: right;">Page 163</p> <p>1 MS. ALBEE: Objection, form.</p> <p>2 A. Are you waiting for me?</p> <p>3 Q. Yes.</p> <p>4 A. I'm sorry. Can you repeat that?</p> <p>5 Q. And this is saying, is it not, that even</p> <p>6 though prices for these NDCs may be inflated, state</p> <p>7 Medicaid programs are not "overpaying" for these</p> <p>8 drugs because the regulations and state plans</p> <p>9 authorize payments for these drugs based upon the</p> <p>10 inflated AWP's for those drugs, is it not?</p> <p>11 A. And you're saying that's what this is</p> <p>12 saying?</p> <p>13 Q. Yes. Is that how you interpret it?</p> <p>14 MS. MARTINEZ: Objection, form.</p> <p>15 MS. MILLER: Objection, form.</p> <p>16 A. I'd prefer not to answer that because</p> <p>17 you're asking me to interpret this.</p> <p>18 Q. I'm asking for your interpretation as</p> <p>19 someone who appears to have been involved in the</p> <p>20 drafting of the document.</p> <p>21 MS. MARTINEZ: Objection, form.</p> <p>22 A. Right. But you're asking me -- this has</p>	<p style="text-align: right;">Page 165</p> <p>1 Q. What do you understand the term</p> <p>2 "overpaid" to mean?</p> <p>3 A. Paying too much.</p> <p>4 Q. Paying too much based upon the relevant</p> <p>5 law at the time?</p> <p>6 MS. MARTINEZ: Objection, form.</p> <p>7 A. You want to say law. Maybe. I don't</p> <p>8 know. I can guess. Paying -- I can't say</p> <p>9 specifically. I can't interpret this. But</p> <p>10 overpaying --</p> <p>11 Q. I'm asking for your interpretation here</p> <p>12 today.</p> <p>13 A. Paying more than what they should be</p> <p>14 paying.</p> <p>15 Q. And this comment is saying that in</p> <p>16 essence OIG's report should not say that paying for</p> <p>17 these drugs based on inflated AWP's was paying more</p> <p>18 than they should be paying, is it not?</p> <p>19 MS. MARTINEZ: Objection, form.</p> <p>20 MS. ALBEE: Objection to form.</p> <p>21 A. It may be saying that, but it sounds like</p> <p>22 they just want the word "overpaid" removed from</p>

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<p style="text-align: right;">Page 166</p> <p>1 there because the comments have more in there than</p> <p>2 just that one sentence.</p> <p>3 Q. You indicated earlier -- you can put that</p> <p>4 away.</p> <p>5 You indicated earlier that in your work</p> <p>6 at CMS you understood the term average wholesale</p> <p>7 price to mean prices published in Blue Book, Red</p> <p>8 Book or other compendia, correct?</p> <p>9 MS. MARTINEZ: Objection, form.</p> <p>10 A. Correct.</p> <p>11 Q. And that is in fact how many state plans</p> <p>12 specifically defined the term average wholesale</p> <p>13 price; am I right?</p> <p>14 MS. MARTINEZ: Objection, form.</p> <p>15 A. I don't know what you mean by defined it.</p> <p>16 They use AWP in their pricing.</p> <p>17 Q. And when you saw states using AWP in</p> <p>18 their pricing you understood them to be referring to</p> <p>19 prices in Blue Book, Red Book or other compendia,</p> <p>20 correct?</p> <p>21 MS. MARTINEZ: Objection, form.</p> <p>22 A. I don't know whether they get their AWP</p>	<p style="text-align: right;">Page 168</p> <p>1 amendment.</p> <p>2 Q. And what is a state plan amendment?</p> <p>3 A. A state plan amendment is sort of a</p> <p>4 snapshot of the state's Medicaid program. And they</p> <p>5 submit this to CMS.</p> <p>6 Q. If we look at section 12 under prescribed</p> <p>7 drugs there's a paragraph B there. Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. It says "EAC is defined as Blue Book</p> <p>10 published average wholesale price (AWP) minus 8</p> <p>11 percent for legend drugs except for DEA schedule II</p> <p>12 drugs which shall be Blue Book published AWP." Do</p> <p>13 you see that?</p> <p>14 A. Yes.</p> <p>15 Q. So in this state plan they specifically</p> <p>16 defined AWP in reference to the Blue Book, correct?</p> <p>17 A. Right.</p> <p>18 Q. And when you reviewed state plans at</p> <p>19 HCFA, when you saw the term AWP you believed they</p> <p>20 were referring to what was in Blue Book or other</p> <p>21 compendia, correct?</p> <p>22 MS. ALBEE: Objection, form.</p>
<p style="text-align: right;">Page 167</p> <p>1 from. I know where I get the AWP, direct price and</p> <p>2 wholesale acquisition cost, from those three</p> <p>3 compendia sources. But I don't know specifically if</p> <p>4 the states use those sources also.</p> <p>5 Q. You're familiar with -- let me mark a</p> <p>6 document.</p> <p>7 (Exhibit Abbott 457 was</p> <p>8 marked for</p> <p>9 identification.)</p> <p>10 BY MR. TORBORG:</p> <p>11 Q. Ms. Gaston, I've handed you a copy of</p> <p>12 what's been marked HHC 008-0083. It's titled "state</p> <p>13 plan under title 19 of the Social Security Act."</p> <p>14 The state is indicated as Tennessee. And there's</p> <p>15 language in the upper right-hand corner that says</p> <p>16 attachment 4.19B.</p> <p>17 My question to you, Ms. Gaston, is</p> <p>18 whether or not you're familiar with this type of</p> <p>19 document.</p> <p>20 A. Yes.</p> <p>21 Q. And what is this type of document?</p> <p>22 A. It's a page from a state's state plan</p>	<p style="text-align: right;">Page 169</p> <p>1 MS. MARTINEZ: Objection, form.</p> <p>2 A. Like I said, I don't know where they get</p> <p>3 their AWP from. It doesn't -- it wouldn't concern</p> <p>4 me because if they detail it in a state plan</p> <p>5 amendment, that's fine. But what we're looking at</p> <p>6 is their methodology they're submitting to CMS.</p> <p>7 Q. Okay. You can put that to the side.</p> <p>8 When you started working in the pharmacy</p> <p>9 area, Ms. Gaston, of CMS starting in 1991, had you</p> <p>10 had any prior experience with Medicaid's payment for</p> <p>11 drugs?</p> <p>12 A. No.</p> <p>13 Q. Did you receive any reports or other</p> <p>14 information to educate yourself about the issues</p> <p>15 that you would be confronting in your new job?</p> <p>16 A. No.</p> <p>17 Q. You can say for certain that you did not</p> <p>18 review any background material at all?</p> <p>19 A. When I was interviewed by Larry he gave</p> <p>20 me a copy of -- it was like the law, but it</p> <p>21 wasn't -- it was the new legislation, so it was</p> <p>22 something pertaining to the law. That was it.</p>

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<p style="text-align: right;">Page 170</p> <p>1 Q. Do you recall reviewing any reports from 2 the Office of Inspector General? 3 A. No, I don't. 4 Q. Can you say for certain that you did not 5 review them? 6 A. Is this before I was hired? 7 Q. After you were hired and started working 8 in your job. 9 A. Oh. Then what was your question? 10 Q. Did you review reports from the Office of 11 Inspector General relating to reimbursement of 12 drugs? 13 A. Yes. 14 MS. MARTINEZ: Objection, form. Are you 15 asking about the entire '91 to 2003 period, or 16 specifically right in '91 when she started? Because 17 you were going to that early period and then you 18 seemed to open it up. 19 Q. I'd like to ask you to go to Exhibit 307 20 in your book. 21 MS. MARTINEZ: Counsel, you're planning 22 on breaking maybe within the next 10 or 15 minutes</p>	<p style="text-align: right;">Page 172</p> <p>1 AFTERNOON SESSION 2 (2:04 p.m.) 3 * * * * * 4 Whereupon, 5 SUE GASTON, 6 the witness testifying at the time of 7 recess, having been previously duly sworn, 8 was further examined and testified as 9 follows. 10 * * * * * 11 THE VIDEOGRAPHER: This is the beginning 12 of tape 4 in the deposition of Ms. Gaston. On the 13 record at 2:04. 14 EXAMINATION RESUMED BY COUNSEL FOR THE 15 ABBOTT LABORATORIES 16 BY MR. TORBORG: 17 Q. Welcome back, Ms. Gaston. 18 A. Thank you. 19 Q. At the time we broke I had asked you to 20 flip to Abbott Exhibit 307 in the orange binders. 21 And this appears to me to be an action transmittal 22 that contains a report from the HHS Office of</p>
<p style="text-align: right;">Page 171</p> <p>1 or something? 2 MR. TORBORG: Why don't we just go ahead 3 and take our lunch break now. Would you like to do 4 that, Ms. Gaston? 5 THE WITNESS: Sure. 6 MR. TORBORG: Why don't we take our lunch 7 break now. 8 THE VIDEOGRAPHER: This is the end of 9 tape 3. Off the record at 1:02. 10 (Whereupon, at 1:02 p.m. a lunch recess 11 was taken.) 12 13 14 15 16 17 18 19 20 21 22</p>	<p style="text-align: right;">Page 173</p> <p>1 Inspector General. And have you had a chance to 2 look at this document to tell me whether or not you 3 have seen this before? 4 A. I've glanced at it, and it doesn't look 5 familiar. 6 Q. If I could ask you to go then to Abbott 7 Exhibit 81 in the orange binders. Ms. Gaston, I ask 8 that you take a look at that document. It's titled 9 "Prescription Drug Prices: Are We Getting Our 10 Money's Worth? A Majority Staff report of the 11 Special Committee On Aging in the United States 12 Senate," dated in 1989. 13 A. (Reading.) This doesn't look familiar. 14 Q. I'd like to ask you to go to page 10 of 15 the study. There's no Bates numbers on it but I 16 think you'll see the page number is on the actual 17 document if you go in a few pages. Were you able to 18 find it? 19 A. Yes. 20 Q. Specifically I draw your attention to 21 finding 7. Do you see that at the bottom of the 22 page?</p>

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<p style="text-align: right;">Page 174</p> <p>1 A. Yes.</p> <p>2 Q. Where it states "There are two markets in</p> <p>3 the United States for most big-selling prescription</p> <p>4 drugs: a price competitive market characterized by</p> <p>5 deep discounts off the published list price, and a</p> <p>6 high-priced market where retail customers, Medicare</p> <p>7 and Medicaid purchase those prescription drugs." Do</p> <p>8 you have an understanding of what that finding is</p> <p>9 saying, Ms. Gaston?</p> <p>10 A. No.</p> <p>11 Q. If we go, please, to page 11, under the</p> <p>12 first bullet there is a bullet that's discussing the</p> <p>13 Department of Veterans Affairs. Do you see that?</p> <p>14 A. Yes, I do.</p> <p>15 Q. The first paragraph under that bullet, I</p> <p>16 guess subparagraph, states "DVA" -- which is defined</p> <p>17 above as the Department of Veterans Affairs --</p> <p>18 "achieves an average discount of 41 percent off the</p> <p>19 manufacturer's published 'average wholesale price'</p> <p>20 for single source drugs (those still under patent),</p> <p>21 and an average of 67 percent off the published AWP</p> <p>22 for multiple source drugs." Do you see that?</p>	<p style="text-align: right;">Page 176</p> <p>1 contract with wholesalers to purchase prescription</p> <p>2 drugs from a predetermined list are able to achieve</p> <p>3 discounts of up to 99 percent off manufacturer's</p> <p>4 published 'average wholesale price' even for brand</p> <p>5 name drugs." Do you see that?</p> <p>6 A. Yes, I do.</p> <p>7 Q. Did you become aware of that during your</p> <p>8 work at CMS?</p> <p>9 A. No.</p> <p>10 Q. How do you know that you did not become</p> <p>11 aware of it, as opposed to just you may have known</p> <p>12 about it but forgot about it?</p> <p>13 MS. MARTINEZ: Objection, form.</p> <p>14 A. It doesn't sound familiar to me.</p> <p>15 Q. But you may have become aware of it, you</p> <p>16 just don't remember today?</p> <p>17 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>18 MS. MARTINEZ: Objection, form.</p> <p>19 A. It doesn't sound familiar to me.</p> <p>20 Q. Did you at some point learn that</p> <p>21 hospitals, health maintenance organizations and</p> <p>22 nursing homes received deeper discounts in</p>
<p style="text-align: right;">Page 175</p> <p>1 A. Yes.</p> <p>2 Q. Do you recall becoming aware of that</p> <p>3 finding during the course of your work at CMS?</p> <p>4 A. No, I don't.</p> <p>5 Q. Did your office receive copies of reports</p> <p>6 prepared by the General Accounting Office or other</p> <p>7 congressional committees?</p> <p>8 MS. MARTINEZ: Objection, form.</p> <p>9 Q. Or congressional committees?</p> <p>10 MS. MARTINEZ: Objection, form.</p> <p>11 A. We received GAO reports.</p> <p>12 Q. And was it your practice to review those</p> <p>13 reports?</p> <p>14 MS. MARTINEZ: Objection, form.</p> <p>15 A. At times. Not every report.</p> <p>16 Q. If it related to Medicaid payment for</p> <p>17 prescription drugs, would that be something that in</p> <p>18 your practice you would have reviewed?</p> <p>19 A. It's possible.</p> <p>20 Q. Finally in the last paragraph, page 11,</p> <p>21 the last bullet states "Hospitals, health</p> <p>22 maintenance organizations and nursing homes that</p>	<p style="text-align: right;">Page 177</p> <p>1 purchasing drugs?</p> <p>2 A. I'm not aware of that.</p> <p>3 Q. That's not something you recall being</p> <p>4 discussed in any OIG reports?</p> <p>5 A. I don't recall.</p> <p>6 Q. I'd like to ask you to go to Abbott</p> <p>7 Exhibit 129. Abbott Exhibit 129 is an OIG report</p> <p>8 titled "Comparison of Reimbursement Prices for</p> <p>9 Multiple Source Prescription Drugs in the United</p> <p>10 States and Canada" bearing the report number</p> <p>11 OEI-03-91-00470. Do you have an understanding of</p> <p>12 what that number signifies, Ms. Gaston?</p> <p>13 A. The report number?</p> <p>14 Q. Yes.</p> <p>15 A. No.</p> <p>16 Q. If you would go to the last page of this</p> <p>17 document, the second-to-last page, there's a comment</p> <p>18 there, a memo from Richard Kusserow dated March 12th</p> <p>19 1991. Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. I just wanted to put a time frame in mind</p> <p>22 regarding this report. Would you take a look at</p>

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<p style="text-align: right;">Page 178</p> <p>1 this report and let me know if it's something that</p> <p>2 you recall reviewing?</p> <p>3 A. You said to Kusserow? Okay. And you're</p> <p>4 talking about the one from Kusserow?</p> <p>5 Q. I'm sorry. I'm asking you to take a look</p> <p>6 at the actual OIG report that starts at the</p> <p>7 beginning of the document. Does the front page of</p> <p>8 your document say "comparison of reimbursement</p> <p>9 prices"?</p> <p>10 A. Yes.</p> <p>11 Q. If you would take a look at this OIG</p> <p>12 report and let me know if you recall reviewing it</p> <p>13 before, the actual report, not just the memo.</p> <p>14 A. (Reading.) No. I don't remember this</p> <p>15 report.</p> <p>16 Q. From your glance does the document appear</p> <p>17 to compare government reimbursement prices for</p> <p>18 multiple source drugs in the United States and</p> <p>19 Ontario, Canada?</p> <p>20 A. That's what it appears to be doing.</p> <p>21 Q. And does it appear to relate to the</p> <p>22 Medicaid program?</p>	<p style="text-align: right;">Page 180</p> <p>1 correct?</p> <p>2 A. Correct.</p> <p>3 Q. This is something that happened before</p> <p>4 2003, correct, when you were working --</p> <p>5 A. Correct.</p> <p>6 Q. -- not in the current job?</p> <p>7 A. Correct.</p> <p>8 Q. And can you give me any estimate of</p> <p>9 whether that visit happened at the beginning of your</p> <p>10 tenure in that job, middle or end?</p> <p>11 A. No.</p> <p>12 Q. It's been too long ago for you to</p> <p>13 remember those details?</p> <p>14 A. Correct.</p> <p>15 Q. And do you recall where the visitor was</p> <p>16 from? Was he affiliated with any organization in</p> <p>17 particular?</p> <p>18 A. I can't remember.</p> <p>19 Q. Was he from Canada?</p> <p>20 A. I can't remember.</p> <p>21 Q. Did he supply you with any information,</p> <p>22 like any actual written information?</p>
<p style="text-align: right;">Page 179</p> <p>1 A. Yes.</p> <p>2 Q. That is not something that you recall at</p> <p>3 all; is that right?</p> <p>4 A. Correct.</p> <p>5 Q. Do you recall in your work at CMS any</p> <p>6 discussion of drug pricing information available in</p> <p>7 Canada?</p> <p>8 A. Yes.</p> <p>9 Q. Tell me what you recall about that.</p> <p>10 A. I just remember that we had someone, a</p> <p>11 visitor, come in and talk about how Canada -- the</p> <p>12 drug pricing in Canada.</p> <p>13 Q. Do you recall who that visitor was?</p> <p>14 A. No.</p> <p>15 Q. Do you recall when that visit happened?</p> <p>16 A. No.</p> <p>17 Q. Do you recall who else was at the</p> <p>18 meeting?</p> <p>19 A. Larry Reed.</p> <p>20 Q. Anyone else?</p> <p>21 A. I don't recall.</p> <p>22 Q. So at least yourself and Larry Reed,</p>	<p style="text-align: right;">Page 181</p> <p>1 A. I can't remember.</p> <p>2 Q. Do you recall what the purpose of the</p> <p>3 meeting was? Why was he coming to visit you?</p> <p>4 A. From my recollection, we would have</p> <p>5 visitors come in sometimes just to discuss how</p> <p>6 they -- I guess how they handled their health care</p> <p>7 and what they do in their countries. Just an</p> <p>8 overview.</p> <p>9 Q. Do you recall in this particular visit</p> <p>10 was something that HCFA had requested or was just</p> <p>11 someone approached you about a possible visit?</p> <p>12 A. My recollection is they contacted us for</p> <p>13 a visit.</p> <p>14 Q. And was it an in-person meeting, you</p> <p>15 said?</p> <p>16 A. Excuse me?</p> <p>17 Q. Was it an in-person meeting?</p> <p>18 A. Correct.</p> <p>19 Q. And how long was the meeting?</p> <p>20 A. I can't say. I can't recall.</p> <p>21 Q. And do you recall anything you did as a</p> <p>22 result of this meeting? Any steps you took or</p>

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<p style="text-align: right;">Page 182</p> <p>1 anything else you did?</p> <p>2 A. No. Don't recall.</p> <p>3 Q. Was it an informational type meeting?</p> <p>4 A. From what I remember, it was an</p> <p>5 information sharing meeting.</p> <p>6 Q. Do you recall sharing any information or</p> <p>7 advising state and Medicaid programs of this visit?</p> <p>8 A. You're saying advising any --</p> <p>9 Q. Advising any state Medicaid officials of</p> <p>10 this visit?</p> <p>11 A. No. In the that I remember.</p> <p>12 Q. Okay. Could I ask you to go to Abbott</p> <p>13 Exhibit 79? For the record, this starts with a</p> <p>14 letter dated November 6th 1992 from Bryan Mitchell</p> <p>15 to William Toby, subject: physician's cost for</p> <p>16 chemotherapy drugs. And attached is a copy of the</p> <p>17 report. Ms. Gaston, if you would take a look at</p> <p>18 that document and let me know if this is a document</p> <p>19 you recall getting.</p> <p>20 A. (Reading.) This report does not look</p> <p>21 familiar.</p> <p>22 Q. If I could ask you to go to the Bates</p>	<p style="text-align: right;">Page 184</p> <p>1 A. Because, I mean, you're asking --</p> <p>2 generally -- well, this focuses on Medicare. But I</p> <p>3 don't know what physicians pay for drugs and I don't</p> <p>4 get involved in that.</p> <p>5 Q. You were focused on pharmacies in</p> <p>6 Medicaid; is that right?</p> <p>7 A. Well, and setting prices for the state</p> <p>8 Medicaid agencies for Medicaid purposes.</p> <p>9 Q. Okay. And Medicaid purposes you were</p> <p>10 focused on pharmacies; is that right?</p> <p>11 A. Well, yeah, basically.</p> <p>12 Q. And physicians as well?</p> <p>13 A. For the retail class of trade, I think</p> <p>14 it's a general term that we used. But prices that</p> <p>15 we set I don't know what pharmacies are going to be</p> <p>16 paying or what physicians are going to be paying.</p> <p>17 Q. Did you come to learn at some point that</p> <p>18 AWP was not a reliable indicator of what pharmacies</p> <p>19 paid to acquire drugs?</p> <p>20 MS. MARTINEZ: Objection, form.</p> <p>21 A. It was my understanding that AWP is one</p> <p>22 of the higher of the prices that are in the</p>
<p style="text-align: right;">Page 183</p> <p>1 page ending 324. Is there a page on there or no?</p> <p>2 Is there a Bates page on that copy? There may not</p> <p>3 be.</p> <p>4 MS. MARTINEZ: No.</p> <p>5 Q. Why don't I ask you to go to -- if you go</p> <p>6 to the actual fifth page in to the document, it'll</p> <p>7 say "Page 2 - William Toby Jr." at the top.</p> <p>8 A. Okay.</p> <p>9 Q. The first paragraph there OIG wrote "Our</p> <p>10 results indicate that for the physicians surveyed</p> <p>11 the 13 chemotherapy drugs can be purchased at</p> <p>12 amounts below AWP and that AWP is not a reliable</p> <p>13 indicator of the cost of a drug to physicians." Do</p> <p>14 you see that?</p> <p>15 A. Yes.</p> <p>16 Q. And was that something that you came to</p> <p>17 know at some point during your time at CMS that AWP</p> <p>18 was not a reliable indicator of a cost of a drug to</p> <p>19 a physician or a pharmacy?</p> <p>20 MS. MARTINEZ: Objection, form.</p> <p>21 A. I can't answer that.</p> <p>22 Q. Why not?</p>	<p style="text-align: right;">Page 185</p> <p>1 compendia.</p> <p>2 Q. Did you believe it was a reliable</p> <p>3 indicator of what a pharmacy would pay for a drug?</p> <p>4 MS. MARTINEZ: Objection, form.</p> <p>5 A. I used the compendia source and that's</p> <p>6 what I used for making my judgment for setting FUL</p> <p>7 prices.</p> <p>8 Q. And the FUL prices -- your understanding</p> <p>9 of the regulations with the FUL is that you're</p> <p>10 required to use the prices contained in the</p> <p>11 compendia, correct?</p> <p>12 A. Correct.</p> <p>13 Q. My question is a little bit different.</p> <p>14 And that is, did you believe that the AWP prices</p> <p>15 listed in the compendia were a reliable indicator of</p> <p>16 the cost to providers to purchase drugs?</p> <p>17 MS. MARTINEZ: Objection, form.</p> <p>18 A. When you say a reliable indicator -- so</p> <p>19 are you saying -- can you explain that to me?</p> <p>20 Q. Do you know what the term "reliable"</p> <p>21 means?</p> <p>22 A. Yeah.</p>

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<p style="text-align: right;">Page 186</p> <p>1 Q. What is your understanding of what the</p> <p>2 term reliable means?</p> <p>3 A. That it would be something that somebody</p> <p>4 could rely on.</p> <p>5 Q. And "indicator." Do you have an</p> <p>6 understanding of what indicator means?</p> <p>7 A. Yes.</p> <p>8 Q. What is your understanding of what that</p> <p>9 means?</p> <p>10 A. That it's something that somebody could</p> <p>11 use I guess to judge, to base a judgment on.</p> <p>12 Q. Okay. So my question I guess restated</p> <p>13 would be did you believe AWP's in the compendia were</p> <p>14 something that could be relied upon to provide an</p> <p>15 indication of what a pharmacy paid for a drug?</p> <p>16 MS. MARTINEZ: Objection, form.</p> <p>17 A. I couldn't say that, because I don't</p> <p>18 know -- I don't know what pharmacies pay for drugs</p> <p>19 and every pharmacy pays something different for</p> <p>20 drugs. So I couldn't make that statement.</p> <p>21 Q. And because every -- well, did you learn</p> <p>22 that pharmacies paid different amounts for the same</p>	<p style="text-align: right;">Page 188</p> <p>1 BY MR. TORBORG:</p> <p>2 Q. All right, Ms. Gaston. I've handed you</p> <p>3 as what has been marked Abbott Exhibit 458 a March</p> <p>4 1993 GAO report titled Outpatient Drug Costs and</p> <p>5 Reimbursements for Selected Pharmacies in Illinois</p> <p>6 and Maryland. And it also says at the top Medicaid.</p> <p>7 MS. MARTINEZ: I'm sorry. Aren't we on</p> <p>8 Exhibit 458?</p> <p>9 MR. TORBORG: Correct. You can put that</p> <p>10 aside. I'm done with that.</p> <p>11 THE WITNESS: You didn't ask me any</p> <p>12 questions about this.</p> <p>13 MR. TORBORG: I just wanted to know if</p> <p>14 you saw it and you didn't. If you want I could go</p> <p>15 back and --</p> <p>16 THE WITNESS: No. That's all right.</p> <p>17 BY MR. TORBORG:</p> <p>18 Q. And before you tell me you don't</p> <p>19 recognize it, I'm going to ask you questions about</p> <p>20 it anyway. So you might as well fess up on this</p> <p>21 one.</p> <p>22 A. I have been fessing up. Okay? Don't do</p>
<p style="text-align: right;">Page 187</p> <p>1 drug? Is that something that you learned?</p> <p>2 A. It was my understanding depending on the</p> <p>3 state, depending on the pharmacy, depending if it's</p> <p>4 a big pharmacy or a small pharmacy, that they</p> <p>5 probably purchased things in different ways and pay</p> <p>6 different prices.</p> <p>7 Q. Did you have any expectation at all, Ms.</p> <p>8 Gaston, of whether or not the AWP prices published</p> <p>9 in the compendia would be a reliable indication of</p> <p>10 what a pharmacy paid for that drug?</p> <p>11 MS. MARTINEZ: Objection, form.</p> <p>12 A. I wouldn't know that.</p> <p>13 Q. Let me ask you to go to Exhibit 82.</p> <p>14 Exhibit 82 contains an OIG report titled Cost of</p> <p>15 Dialysis Related Drugs. I'll ask if you could take</p> <p>16 a look at that document, Ms. Gaston, and let me know</p> <p>17 if you're familiar with that one.</p> <p>18 A. (Reading.) I'm not familiar with this</p> <p>19 report.</p> <p>20 (Exhibit Abbott 458 was</p> <p>21 marked for</p> <p>22 identification.)</p>	<p style="text-align: right;">Page 189</p> <p>1 that. You'll have me in jail.</p> <p>2 (Reading.) This report does not look</p> <p>3 familiar to me.</p> <p>4 Q. Do you recall and was it your practice to</p> <p>5 review at least some GAO reports; is that right?</p> <p>6 A. Correct.</p> <p>7 Q. And how would your office get copies of</p> <p>8 these reports? GAO reports, how would your office</p> <p>9 get copies of them?</p> <p>10 A. I really don't know. If they get them</p> <p>11 directly from GAO I really don't know, unless they</p> <p>12 come down as a control.</p> <p>13 Q. When you say as a control --</p> <p>14 A. It could come down from maybe the center</p> <p>15 director's office if they receive it and it filters</p> <p>16 down to our level.</p> <p>17 Q. Let me ask you to turn toward the end of</p> <p>18 the document. Specifically page 17, which is the</p> <p>19 third to the last page.</p> <p>20 A. In the document?</p> <p>21 Q. In the document, yes. The title of the</p> <p>22 page is "major contributors to this fact sheet"?</p>

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<p style="text-align: right;">Page 190</p> <p>1 A. Okay.</p> <p>2 Q. On the right it says "Human resources</p> <p>3 division" in Washington, D.C., and it lists two</p> <p>4 names there. John Hansen and Joel Hamilton. Do you</p> <p>5 know who those two individuals are?</p> <p>6 A. No.</p> <p>7 Q. And have you ever spoken with or met any</p> <p>8 of the people listed below from the Chicago regional</p> <p>9 office, Karyn Bell, Patricia Barry, Joseph Klauke or</p> <p>10 Susan Thillman?</p> <p>11 A. Not that I remember.</p> <p>12 Q. How about a woman by the name of Janet</p> <p>13 Skiles? Do you remember that name?</p> <p>14 A. No.</p> <p>15 Q. Okay. If I could ask you to page 1 of</p> <p>16 the report, the first paragraph discusses the</p> <p>17 Omnibus Budget Reconciliation Act of 1990. Then</p> <p>18 skipping on a couple sentences this refers to a</p> <p>19 provision that required GAO to "conduct a study of</p> <p>20 drug purchasing and billing practices of hospitals,</p> <p>21 other institutional facilities, health maintenance</p> <p>22 organizations and retail pharmacies."</p>	<p style="text-align: right;">Page 192</p> <p>1 the next page. And that paragraph indicates "The</p> <p>2 following table shows the prices that each of the</p> <p>3 five pharmacies, two hospital outpatient pharmacies</p> <p>4 and three nursing home pharmacies, paid per unit for</p> <p>5 those drugs on the state Medicaid program's top 50</p> <p>6 list of outpatient drugs for the year ending October</p> <p>7 31, '91. And then it goes on.</p> <p>8 And the last sentence says it compares</p> <p>9 each drug's average -- it also shows each drug's</p> <p>10 average wholesale price. Do you see that?</p> <p>11 A. Correct.</p> <p>12 Q. Do you recall seeing tables like this in</p> <p>13 reports that would compare what somebody paid for a</p> <p>14 drug versus its AWP?</p> <p>15 A. I don't recall.</p> <p>16 Q. Is it possible you would have reviewed</p> <p>17 such material, you just don't recall it here today?</p> <p>18 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>19 A. It's possible, but I just don't recall.</p> <p>20 Q. And do you have an understanding of what</p> <p>21 this table is showing?</p> <p>22 A. I mean, a basic understanding, but --</p>
<p style="text-align: right;">Page 191</p> <p>1 Do you recall there being a provision in</p> <p>2 OBRA requiring the GAO to do some studies of what</p> <p>3 these kind of organizations were paying for drugs?</p> <p>4 A. I'd have to see the statute that was out</p> <p>5 there at that time. There were some provisions in</p> <p>6 the back of statute, but I can't remember what they</p> <p>7 required.</p> <p>8 Q. Let's go to the next sentence. The next</p> <p>9 paragraph indicates that they are comparing -- I'm</p> <p>10 paraphrasing here. That they are comparing drug</p> <p>11 purchase cost and Medicaid reimbursements in two</p> <p>12 states, Illinois and Maryland, and that also -- the</p> <p>13 last sentence of that paragraph states "We also</p> <p>14 compared the prices that pharmacies paid to the</p> <p>15 drugs' average wholesale prices (AWP). AWP</p> <p>16 represents the price pharmacies would pay if they</p> <p>17 did not receive discounts from manufacturers."</p> <p>18 I'd ask you to take a look at, to see if</p> <p>19 it refreshes your recollection at all, some</p> <p>20 attachments at the end of the document, appendix 2</p> <p>21 on page 12 of the report. And there's a paragraph</p> <p>22 that precedes a table that goes from this page to</p>	<p style="text-align: right;">Page 193</p> <p>1 Q. What is your understanding of what it's</p> <p>2 showing?</p> <p>3 A. It's showing what it says up in the</p> <p>4 wording, but it has AWP on the right-hand side. And</p> <p>5 it's doing comparisons of two hospital outpatient</p> <p>6 pharmacies and three nursing home pharmacies and</p> <p>7 what they paid per unit for drugs that are listed on</p> <p>8 the left-hand side.</p> <p>9 Q. So if you look at number 3, for</p> <p>10 example -- do you know how to pronounce that?</p> <p>11 A. No. You can do a good job of that.</p> <p>12 Q. Diphenhydramine shows a 1.03 per unit.</p> <p>13 Is that how you're reading it?</p> <p>14 A. If that's what they're saying, yeah.</p> <p>15 Q. And then it says one outpatient pharmacy</p> <p>16 purchased that drug at 46 cents and one in-home</p> <p>17 nursing home purchased it for 30 cents per unit; is</p> <p>18 that right?</p> <p>19 A. That's what it's saying.</p> <p>20 Q. Compared to an AWP price of \$1.03 per</p> <p>21 unit?</p> <p>22 A. That's what it's saying.</p>

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<p>1 Q. So this is telling the reader of this</p> <p>2 report that for this drug one nursing home is paying</p> <p>3 less than one-third of the price of the AWP; is that</p> <p>4 right? Am I reading that right?</p> <p>5 A. I'm just reading the numbers here, so</p> <p>6 whatever the numbers reflect, that's what it's</p> <p>7 saying.</p> <p>8 Q. But as it appears, one nursing home paid</p> <p>9 less than one-third of the AWP for this drug?</p> <p>10 A. I'm just going by the numbers. I'm not</p> <p>11 putting percentages on it.</p> <p>12 Q. Okay. 30 cents versus \$1.03?</p> <p>13 A. That's what the chart is saying.</p> <p>14 Q. And you don't recall charts like this?</p> <p>15 A. It doesn't look familiar to me.</p> <p>16 Q. I'm going to ask you, if you would, to go</p> <p>17 to page 6 of this document?</p> <p>18 A. To this last part of it?</p> <p>19 Q. To the actual report.</p> <p>20 MS. MARTINEZ: Counsel, I just want to</p> <p>21 state this objection. If you have a clarification,</p> <p>22 that's fine. But it just seems like you have</p>	<p>1 we reviewed, whether this represents unreasonable</p> <p>2 benefits for the pharmacies is not clear. Neither</p> <p>3 HCFA nor the states have determined what would be an</p> <p>4 appropriate margin between reimbursements and</p> <p>5 costs."</p> <p>6 Do you recall there being discussion at</p> <p>7 HCFA or at the states of when an appropriate margin</p> <p>8 would be between reimbursements and costs?</p> <p>9 MS. MARTINEZ: Objection, form.</p> <p>10 A. I don't remember, no.</p> <p>11 Q. Now, you were from 1991 to 2003 you were</p> <p>12 the Medicaid Bureau?</p> <p>13 A. Correct.</p> <p>14 Q. In the policy side, right?</p> <p>15 A. Correct.</p> <p>16 Q. And the policy side was involved in</p> <p>17 determining how much states should be paying for</p> <p>18 drugs; is that right?</p> <p>19 A. Correct.</p> <p>20 Q. And you don't recall any conversations in</p> <p>21 your position about what an appropriate margin would</p> <p>22 be between reimbursements and cost?</p>
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<p>1 attached a separate document to this. At the back</p> <p>2 there's some other document called state Medicaid --</p> <p>3 MR. TORBORG: That's a copy error.</p> <p>4 MS. MARTINEZ: It's a copy error?</p> <p>5 MR. TORBORG: Yeah. You can remove that.</p> <p>6 I did not want this as part of this exhibit. I'll</p> <p>7 mark it later. I don't know what's going on there.</p> <p>8 If you all would take off that document.</p> <p>9 MS. MARTINEZ: I think it begins here?</p> <p>10 MR. TORBORG: Yeah.</p> <p>11 MS. MARTINEZ: It begins at the page</p> <p>12 that said "state Medicaid pharmacy payments and</p> <p>13 their relation to estimated costs." So that's a</p> <p>14 separate document that seems to be from the Health</p> <p>15 Care Financing Review.</p> <p>16 MR. TORBORG: Yes.</p> <p>17 BY MR. TORBORG:</p> <p>18 Q. Okay. Sorry about that. I'll ask you to</p> <p>19 go to page 6 of the actual report.</p> <p>20 The first full paragraph, the GAO wrote</p> <p>21 "Although total Medicaid reimbursements exceeded the</p> <p>22 pharmacies' total drug purchase costs for the drugs</p>	<p>1 A. No, I don't.</p> <p>2 Q. Do you think any of those conversations</p> <p>3 may have happened and you just don't recall them</p> <p>4 here today?</p> <p>5 MS. MARTINEZ: Objection, form.</p> <p>6 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>7 A. They may have happened.</p> <p>8 Q. Let's go to the next sentence. GAO wrote</p> <p>9 "Further, representatives of all nine pharmacies</p> <p>10 contended that because of insufficient dispensing</p> <p>11 fees they used the excess reimbursements to cover</p> <p>12 the drugs' dispensing costs." Do you see that?</p> <p>13 A. Yes, I do.</p> <p>14 Q. Do you have an understanding of what that</p> <p>15 is saying?</p> <p>16 A. My understanding, yeah.</p> <p>17 Q. And what is your understanding?</p> <p>18 A. It sounds like they're trying to say that</p> <p>19 because the dispensing fees were not high enough,</p> <p>20 that they were using the ingredient cost of the drug</p> <p>21 to compensate for the dispensing fee.</p> <p>22 Q. And is that issue something that you</p>

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<p>1 recall discussing within HCFA and with state 2 Medicaid programs? 3 MS. MARTINEZ: Objection, form. 4 A. Yes, when it concerns state plan 5 amendments. 6 Q. Tell me what you recall about that topic. 7 A. Well, the state plan amendment, states 8 are required to set prices on the ingredient cost of 9 the drug and the dispensing fee should be kept 10 separate. So that was one of the issues that we had 11 to make sure that states were keeping those two 12 separate. 13 Q. And you recall there being issues with 14 states not necessarily keeping them separate; is 15 that fair to say? 16 A. I can't say that. 17 Q. But you recall discussions about using 18 the excess on the ingredient reimbursement to make 19 up for alleged insufficiencies on the dispensing 20 side; is that right? 21 MR. WINGET-HERNANDEZ: Objection, form. 22 A. The conversations that I recall are</p>	<p>1 A. That question -- that would be something 2 routine that you would look at when you were 3 reviewing a state plan amendment. 4 Q. We'll look at some documents later today. 5 Perhaps it will refresh your recollection on that 6 topic. 7 MR. WINGET-HERNANDEZ: Objection to the 8 side-bar remark. 9 Q. If you would look at the next paragraph, 10 it states "From 1976 to 1987 HCFA required states to 11 periodically conduct surveys to gather data on 12 pharmacies' dispensing costs so that they could be 13 used by the states to set dispensing fees. However, 14 in 1987 HCFA rescinded this requirement when it 15 became clear that most states were not conducting 16 the surveys. Because of the fiscal constraints and 17 competing budget priorities, HCFA officials noted 18 that states considered the surveys too expensive. 19 "HCFA officials also noted that because 20 states focused on reducing Medicaid costs, most 21 state programs were not willing to increase 22 dispensing fees regardless of survey results." Do</p>
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<p>1 concerning the state plan amendments. And when we 2 review state plan amendments we need to be assured 3 that the methodology they're using is keeping the 4 ingredient cost and the dispensing fee separate. 5 Q. But do you recall states responding that 6 one reason they were not lowering reimbursement on 7 the ingredient cost was because of a belief that 8 dispensing fees were not adequately? 9 MS. ALBEE: Objection, form. 10 MS. MARTINEZ: Objection, form. 11 A. I can't say is that. 12 Q. Do you recall any -- 13 A. I don't recall any states saying that. 14 Q. Do you recall any written correspondence 15 about that issue with your colleagues at state 16 Medicaid programs? 17 A. I don't recall, no. 18 Q. Was that an issue that came up quite a 19 bit in connection with your work on state plan 20 amendments? 21 MS. ALBEE: Objection to form. 22 MS. MARTINEZ: Objection, form.</p>	<p>1 you see that? 2 A. Yes, I do. 3 Q. Okay. Do you recall anyone making that 4 observation? 5 A. I'm not familiar with that, no. 6 Q. Do you know what HCFA officials would 7 have made this note that I just read? 8 A. I'm not aware. 9 Q. Do you have any idea who it would have 10 been? 11 A. No. 12 Q. Would it have likely been someone who 13 worked with Larry Reed, in that department? 14 MS. MARTINEZ: Objection, form. 15 A. Don't know. 16 Q. Is there any other place in the HCFA 17 hierarchy where one could expect to find someone who 18 was commenting to GAO on these issues? 19 MS. MARTINEZ: Objection, form. 20 A. This is before my time. They're saying 21 from '76 to '87. And I don't know what was 22 occurring in HCFA at that time.</p>

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<p>1 Q. Well, the report is dated 1993, correct?</p> <p>2 A. But they're talking about the surveys and</p> <p>3 all of this going on during this period of time. So</p> <p>4 isn't that what you're asking me?</p> <p>5 Q. Well, let me ask you this. Is there</p> <p>6 anyone else within the HCFA hierarchy who would have</p> <p>7 been making comments to GAO employees regarding</p> <p>8 issues like adequacy of dispensing fees, and</p> <p>9 adequacy of reimbursement?</p> <p>10 A. I don't know. I just know what we did in</p> <p>11 our area.</p> <p>12 Q. Would it be appropriate for states not to</p> <p>13 increase dispensing fees regardless of survey</p> <p>14 results?</p> <p>15 MS. MARTINEZ: Objection, form.</p> <p>16 A. I don't know.</p> <p>17 Q. Who would be able to answer that</p> <p>18 question?</p> <p>19 MS. MARTINEZ: Objection, form.</p> <p>20 A. I don't know. You could ask Larry.</p> <p>21 Q. Well, you were in the policy department</p> <p>22 for 12, 13 years, correct?</p>	<p>1 dispensing fees were higher. But generally from my</p> <p>2 recollection I don't remember responding to an issue</p> <p>3 of a dispensing fee being too low.</p> <p>4 Q. The next paragraph states "HCFA and state</p> <p>5 Medicaid officials agreed that pharmacies must often</p> <p>6 use excess Medicaid reimbursements to cover their</p> <p>7 dispensing costs." Do you see that?</p> <p>8 MS. MARTINEZ: Objection, form.</p> <p>9 A. Yes.</p> <p>10 Q. Do you recall that sentiment being</p> <p>11 expressed during your time at CMS?</p> <p>12 MS. MARTINEZ: Objection, form.</p> <p>13 A. No.</p> <p>14 Q. And do you know who at HCFA would have</p> <p>15 made this comment?</p> <p>16 A. No, I don't.</p> <p>17 Q. Do you have any guess who it would be?</p> <p>18 MS. MARTINEZ: Objection, form.</p> <p>19 A. No.</p> <p>20 Q. Do you know anyone outside of the</p> <p>21 department you worked at from 1991 to 2003 who would</p> <p>22 have been making these comments?</p>
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<p>1 A. Correct.</p> <p>2 Q. And part of your job was to review what</p> <p>3 states were paying for dispensing fees; is that</p> <p>4 right?</p> <p>5 A. That's part of it, yes.</p> <p>6 Q. And what was your understanding of what</p> <p>7 the federal guidelines were with respect to</p> <p>8 dispensing fees?</p> <p>9 A. That it needs to be reasonable and it's</p> <p>10 up to the states to prove whether their dispensing</p> <p>11 fees are reasonable.</p> <p>12 Q. And if the survey indicated that</p> <p>13 dispensing fee was below cost, would that be</p> <p>14 reasonable?</p> <p>15 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>16 MS. MARTINEZ: Objection, form.</p> <p>17 A. I can't answer that.</p> <p>18 Q. Would you need more information to answer</p> <p>19 that?</p> <p>20 A. No, because I don't know -- I know from</p> <p>21 my recollection -- when we did state plan</p> <p>22 amendments, we would address situations where the</p>	<p>1 MS. MARTINEZ: Objection to form.</p> <p>2 A. Outside of the policy area?</p> <p>3 Q. Yes.</p> <p>4 A. I don't know.</p> <p>5 Q. Do you recall if CMS commissioned any</p> <p>6 studies to determine the adequacy of dispensing</p> <p>7 fees?</p> <p>8 A. Like an official study?</p> <p>9 Q. Any study at all, then we'll talk about</p> <p>10 official versus unofficial.</p> <p>11 A. There may have been unofficial canvassing</p> <p>12 of the states for dispensing fees.</p> <p>13 Q. When you say canvassing of the states, do</p> <p>14 you remember to remember to looking to what other</p> <p>15 states are --</p> <p>16 A. Soliciting states to get a feel for what</p> <p>17 their dispensing fees are.</p> <p>18 Q. What do you recall about that?</p> <p>19 A. That's all I recall.</p> <p>20 Q. I'm going to hand you two documents at</p> <p>21 the same time here. They're two different forms of</p> <p>22 the same document.</p>

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<p>1 (Exhibit Abbott 459 and 2 Exhibit Abbott 460 were 3 marked for identification.) 4 BY MR. TORBORG: 5 Q. What I've marked as Abbott Exhibit 459 6 bears the Bates numbers VAC MDL 45005 through 31. 7 What I've marked as Abbott Exhibit 460 does not have 8 Bates numbers. 9 Ms. Gaston, Abbott Exhibit 459 starts out 10 with a cover page from Dr. John and Zack on 11 Ven-A-Care letterhead to T. Reed Stephens, trial 12 attorney with the Department of Justice. And it 13 attaches a document called -- starting at Bates page 14 ending 007 Health Care Financing Review, spring of 15 '94, which appears to be an article attached at the 16 next page titled State Medicaid Pharmacy Payments 17 and Their Relation to Estimated Costs. 18 And the second document I've handed you, 19 Abbott Exhibit 460, is a I think better copy of the 20 actual survey document in that it's not cut off at 21 the side. I'd like to tell me whether or not you've 22 seen -- ever reviewed the actual survey. And while</p>	<p>1 MR. TORBORG: Which I'm sure we will, 2 particularly since the document apparently has been 3 in DOJ's possession for ten years. 4 MS. MARTINEZ: I'm going to object to 5 that. And I'm also objecting to your discussion 6 being part of the record of Ms. Gaston's deposition. 7 MR. TORBORG: Okay. 8 A. So this is what's in here? 9 BY MR. TORBORG: 10 Q. It's a subset, yes. It doesn't have the 11 cover pages on it. 12 A. What was the date of this? 13 Q. If you look at the bottom of Exhibit 14 460 -- 15 A. Okay. 16 Q. -- it says Health Care Financing Review, 17 spring of 1994. 18 A. This looks a little familiar, but that's 19 all I can really say about it. 20 Q. If we work off -- well, first, let me ask 21 you are you familiar with something called the 22 Health Care Financing Review?</p>
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<p>1 you're taking a look at that, these are some 2 comments for counsel. 3 MR. TORBORG: It's disserving to me that 4 this document was not produced by the United States 5 Government. It did not come up in HCFA's document 6 collection. The best I can tell doing due diligence 7 on our side it appears as though the document was 8 housed at some point at the Office of Research and 9 Demonstrations at HCFA, something that -- I was not 10 aware of that office before, nor do I know whose 11 this is. 12 But I would request you search that 13 particular location for any other documents. I 14 think if you would review the document you would see 15 it is quite relevant to the issues at play in this 16 case. So either it didn't come up in your search or 17 it was -- just didn't exist anymore for whatever 18 reason. And as well as any other documents that may 19 pertain to this time. I'll follow up with a letter. 20 MS. MARTINEZ: I'm sure we could have 21 just talked about that outside Ms. Gaston's 22 testimony.</p>	<p>1 A. I'd have to see it to know. Is it a 2 publication? 3 Q. It appears to me as though it is. 4 A. Excuse me? 5 Q. It appears to me as though it is, but 6 that's why I'm asking a little bit more about it to 7 you. 8 A. If I could visually see it it might look 9 familiar. 10 Q. I don't have a copy of one. 11 A. Okay. I'm not familiar with it then. 12 Q. Okay. Do you know a Kathleen Gondeck? 13 A. Yes. 14 Q. Okay. Who is she? 15 A. She used to work in ORD, Office of 16 Research and Development. I don't think they're 17 call ORD any longer. 18 Q. Do you know what they're called now? 19 A. No. 20 Q. Is it Office of Research and 21 Demonstrations? 22 A. Demonstrations, yeah. See? You know.</p>

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<p>1 Q. I know what this document tells me.</p> <p>2 A. Okay.</p> <p>3 Q. Nothing more. What was Ms. Gondeck's</p> <p>4 role at HCFA?</p> <p>5 A. I just know that she worked in ORD. I</p> <p>6 think she might have worked on some research in the</p> <p>7 drug area. That's all I know.</p> <p>8 Q. Was it something that she worked on more</p> <p>9 than one report on, to your knowledge?</p> <p>10 A. I don't know.</p> <p>11 Q. And is she still with HCFA today?</p> <p>12 A. It's my understanding she's not.</p> <p>13 Q. Do you know what she's doing today?</p> <p>14 A. Years ago she left. I think she's</p> <p>15 working for a pharmaceutical company.</p> <p>16 Q. Do you know which one?</p> <p>17 A. No.</p> <p>18 Q. If you would take a quick look at this</p> <p>19 document and just see if it helps refresh your</p> <p>20 recollection at all on its contents. The document</p> <p>21 is titled "State Medicaid Pharmacy Payments and the</p> <p>22 Relation to Estimated Costs." Do you have an</p>	<p>1 Q. But do you agree that's what this study</p> <p>2 appears to be showing?</p> <p>3 MS. ALBEE: Objection, form.</p> <p>4 MS. MARTINEZ: Objection, form.</p> <p>5 A. Without reading the whole study, it</p> <p>6 appears that what they're saying here in the</p> <p>7 introduction is what they're trying to address.</p> <p>8 Q. Do you recall how this study was used at</p> <p>9 all in HCFA's administration of the Medicaid</p> <p>10 program?</p> <p>11 MS. MARTINEZ: Objection, form.</p> <p>12 MS. ALBEE: Objection, form.</p> <p>13 A. No.</p> <p>14 Q. I'm going to ask you to go to page 28 of</p> <p>15 the study. The little page number. It starts on</p> <p>16 page 25 of the total publication, but specifically</p> <p>17 page 28 of the publication.</p> <p>18 A. It says data?</p> <p>19 Q. Yeah, data.</p> <p>20 This refers to the fact that a</p> <p>21 significant amount of information was drawn from</p> <p>22 databases available through IMS America. Do you see</p>
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<p>1 understanding as you review this what this study is</p> <p>2 attempting to do?</p> <p>3 A. No, unless I read through the study. I</p> <p>4 don't recall that.</p> <p>5 Q. If you go to the third sentence of the</p> <p>6 introductory section of the article, it states</p> <p>7 "Congress mandated a study of the adequacy of</p> <p>8 Medicaid payments to pharmacies. In this study</p> <p>9 several data sources were reviewed to develop 1991</p> <p>10 estimates of average pharmacy ingredient and</p> <p>11 dispensing costs. A simulation was used to estimate</p> <p>12 the amounts states pay. Nationally simulated</p> <p>13 payments averaged 96 percent of estimated costs</p> <p>14 overall, but were lower for dispensing cost (79</p> <p>15 percent) and higher for ingredient costs (102</p> <p>16 percent)."</p> <p>17 Do you recall a study that sought to look</p> <p>18 at the reimbursement paid to providers on a more</p> <p>19 combined basis, both on the ingredient cost side and</p> <p>20 on the dispensing cost side?</p> <p>21 MS. MARTINEZ: Objection, form.</p> <p>22 A. No.</p>	<p>1 that?</p> <p>2 A. Yes.</p> <p>3 Q. Do you know what that is, what IMS is?</p> <p>4 A. I've heard of them. I can't say</p> <p>5 specifically what they do.</p> <p>6 Q. Have you ever discussed the availability</p> <p>7 of IMS data with anyone else in HCFA?</p> <p>8 A. Not that I recall.</p> <p>9 Q. Do you know if this data was available</p> <p>10 for purchase?</p> <p>11 A. I'm not that familiar with IMS.</p> <p>12 Q. Are you familiar with a publication</p> <p>13 called the Lily Digest?</p> <p>14 A. No.</p> <p>15 Q. Okay. I'd like to ask you -- you can put</p> <p>16 that aside. I'm going to be asking you next about</p> <p>17 Abbott Exhibit 284.</p> <p>18 Okay. Ms. Gaston, after you've had a</p> <p>19 chance to take a look at this document which is some</p> <p>20 pages from the Federal Register dated July 31, 1987,</p> <p>21 in particular it is a final rule titled Medicare and</p> <p>22 Medicaid Programs Limits on payments for Drugs. And</p>

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<p style="text-align: right;">Page 214</p> <p>1 as you might guess from this document, I'm now 2 moving to the subject of federal upper limits for 3 the series of questions for you on this exhibit. 4 My first question will be if you're 5 familiar with this regulation. 6 A. I've seen it before. I'm not that 7 familiar with it at this point. 8 Q. But it's something that you would have 9 reviewed in connection with your role in the federal 10 upper limit program; is that fair to say? 11 MS. MARTINEZ: Objection, form. I just 12 want to clarify. The document, the Federal Register 13 has the regulation at the end and the beginning part 14 is the preamble and the issuance of it. The 15 regulation is towards the end. 16 A. I would be more familiar with the reg. 17 I'm sure that I probably had the preamble available 18 to me. But working on the federal upper limit we 19 would actually use the reg. 20 Q. Okay. So if I could ask you to go to 21 page 687 -- 22 A. What?</p>	<p style="text-align: right;">Page 216</p> <p>1 department rules are intended to ensure that the 2 federal government acts as a prudent buyer for drugs 3 under certain federal health programs." Do you see 4 that? 5 A. Yes, I do. 6 Q. And is it your understanding that federal 7 upper limits applied to certain multiple source 8 drugs that satisfy criteria; is that right? 9 A. Correct. 10 Q. And why would you need to establish an 11 upper limit for multiple source drugs? 12 MR. WINGET-HERNANDEZ: Objection, form. 13 MS. MARTINEZ: Objection, form. 14 Q. Do you have an understanding of what the 15 purpose of the FUL program was? 16 A. Yes. 17 Q. What was your understanding? 18 A. To set a reimbursement amount for states 19 to achieve savings for states and Medicaid. 20 Q. Why not just use the average wholesale 21 price of these multiple source drugs to set the 22 reimbursement amount?</p>
<p style="text-align: right;">Page 215</p> <p>1 Q. 687. The Bates page 687 in the bottom 2 right-hand corner. 3 A. Okay. 4 Q. The second column there is a section 5 called part 447, payments for services? 6 A. Correct. 7 Q. And there's the rest of that page and 8 then the next page, is that the actual federal upper 9 limit regulation -- 10 A. Yes. 11 Q. -- amongst other things? 12 A. Right. 13 Q. I take it you had no involvement in the 14 drafting of this regulation prior to its issuance. 15 Is that fair to say? 16 A. Correct. 17 Q. The summary, if you go back to the first 18 page of Abbott Exhibit 284, there's a section in the 19 first column that says "background of the existing 20 system." Do you see that? 21 A. Yes. 22 Q. The second paragraph there says "The</p>	<p style="text-align: right;">Page 217</p> <p>1 MS. MARTINEZ: Objection, form. 2 A. Because the regulations say to use the 3 lowest price in the published compendia. 4 Q. Do you have an understanding of why this 5 regulation existed, why you didn't just use the 6 average wholesale price as published in the 7 compendia? 8 MR. WINGET-HERNANDEZ: Objection to form. 9 MS. MARTINEZ: Objection, form. 10 A. I don't understand the rationale. I had 11 nothing to do with the development of the 12 regulation. 13 Q. So in your work on federal upper limits 14 you had no idea of what the purpose of the program 15 was? 16 A. The purpose of the program is to achieve 17 savings. I don't know the purpose of the statement 18 you made before, of the pricing, you know, what was 19 involved in the methodology. I understand the 20 purpose of the program. 21 Q. And it was to achieve savings on payment 22 for multiple source drugs, correct?</p>

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<p>1 A. Yes.</p> <p>2 Q. And did you understand that the average</p> <p>3 wholesale price for multiple source drugs in</p> <p>4 particular was not a reliable indicator of the cost</p> <p>5 at which pharmacies and physicians purchased drugs?</p> <p>6 MS. MARTINEZ: Objection to form.</p> <p>7 MS. ALBEE: Objection to the form.</p> <p>8 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>9 A. As I stated before, my understanding is</p> <p>10 that I looked at average wholesale price, direct</p> <p>11 price, wholesale acquisition costs, the prices that</p> <p>12 were available in the compendia, and generally</p> <p>13 speaking the average wholesale price was a higher</p> <p>14 price at that point others.</p> <p>15 Q. Did you have an understanding that the</p> <p>16 difference between average wholesale price published</p> <p>17 in the compendia and what people were buying the</p> <p>18 drugs for was particularly variable when it came to</p> <p>19 multiple source drugs as opposed to sole source</p> <p>20 drugs?</p> <p>21 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>22 MS. ALBEE: Objection, form.</p>	<p>1 A. Just what they're saying.</p> <p>2 Q. What are they saying?</p> <p>3 A. So independently I guess states on their</p> <p>4 own shouldn't apply the 150 percent markup.</p> <p>5 Q. If you go to the next paragraph, the</p> <p>6 second full sentence starts with "since." Do you</p> <p>7 see that?</p> <p>8 A. No.</p> <p>9 Q. "Since we are not placing" --</p> <p>10 A. Where are you?</p> <p>11 Q. The next paragraph down about eight lines</p> <p>12 down.</p> <p>13 A. The next paragraph down?</p> <p>14 Q. Yeah.</p> <p>15 A. Okay. "Since we are not"? Okay.</p> <p>16 Q. "Since we are not placing maximum payment</p> <p>17 limits on individual drugs, drugs with high</p> <p>18 compendia prices could generate extremely high</p> <p>19 payment levels. Unless an agency's payment</p> <p>20 methodology ensured otherwise, a Medicaid agency</p> <p>21 could end up paying inappropriately high rates for</p> <p>22 some drugs while still being in compliance with the</p>
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<p>1 MS. MARTINEZ: Objection, form.</p> <p>2 A. I can't say that.</p> <p>3 Q. Is that something that you were made</p> <p>4 aware of in multiple OIG reports?</p> <p>5 MS. MARTINEZ: Objection, form.</p> <p>6 A. It's mentioned in the OIG reports, yes.</p> <p>7 Q. Let me ask you to look at page 685 of</p> <p>8 this document, the Bates page ending in 685. The</p> <p>9 last column, the first full paragraph starts with</p> <p>10 "stage agencies." Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. It says "State agencies should determine</p> <p>13 independent of the 150 percent formula appropriate</p> <p>14 payment levels for the listed multiple source drugs.</p> <p>15 We would not expect a state agency to adopt directly</p> <p>16 the upper limit methodology as a payment method</p> <p>17 because it does not gear payments to markups</p> <p>18 appropriate to the actual costs of acquiring and</p> <p>19 dispensing these drugs." Do you see that?</p> <p>20 A. Yes, I do.</p> <p>21 Q. Do you have an understanding of what that</p> <p>22 means?</p>	<p>1 aggregate upper limit.</p> <p>2 "Nevertheless, we believe states may</p> <p>3 establish maximum payment limits in order to offset</p> <p>4 the minimum payment levels necessary to ensure</p> <p>5 reasonable compensation for very low priced drugs."</p> <p>6 Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. Do you have an understanding of what that</p> <p>9 last sentence means, establishing minimum payment</p> <p>10 levels necessary to ensure reasonable compensation</p> <p>11 for very low priced drugs?</p> <p>12 A. Well, my understanding of what they're</p> <p>13 trying to say is that states have the flexibility to</p> <p>14 set a MAC on drugs that they feel are not priced</p> <p>15 appropriately.</p> <p>16 Q. Do you know what they're talking about or</p> <p>17 how do you interpret the comment reasonable</p> <p>18 compensation for very low priced drugs?</p> <p>19 A. That if they feel that the drug cannot be</p> <p>20 obtained in their state because the price is low,</p> <p>21 that they have the flexibility to set a MAC on a</p> <p>22 drug so that it will be obtainable within their</p>

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<p>1 state.</p> <p>2 (Exhibit Abbott 461 was</p> <p>3 marked for</p> <p>4 identification.)</p> <p>5 MR. TORBORG: I'm told that we have five</p> <p>6 minutes left on the tape and it's within about an</p> <p>7 hour. So let's go ahead and take a break here.</p> <p>8 THE VIDEOGRAPHER: This is the end of</p> <p>9 tape 4. Off the record at 3:17.</p> <p>10 (Recess.)</p> <p>11 THE VIDEOGRAPHER: This is the beginning</p> <p>12 of tape 5 in the deposition of Ms. Gaston. On the</p> <p>13 record at 3:43.</p> <p>14 MR. TORBORG: Welcome back, Ms. Gaston.</p> <p>15 THE WITNESS: Thank you.</p> <p>16 MR. TORBORG: I wanted to cover</p> <p>17 something, some housekeeping matters on the record</p> <p>18 very quickly. I understand from Ms. Martinez that</p> <p>19 there are some additional documents from Ms.</p> <p>20 Gaston's files or legacy files that are yet to be</p> <p>21 produced. Is that right?</p> <p>22 MS. MARTINEZ: Yes.</p>	<p>1 you said from 1991 through 2003 when you were doing</p> <p>2 that, correct?</p> <p>3 A. Correct.</p> <p>4 Q. And those three people were -- three</p> <p>5 additional people were Peter Rodler, Cindy Bergin</p> <p>6 and Gail Sexton?</p> <p>7 A. Gail Sexton worked on the FULs after</p> <p>8 2003.</p> <p>9 Q. Did she have any involvement with FULs</p> <p>10 prior to 2003?</p> <p>11 A. No.</p> <p>12 Q. What was she doing prior to 2003?</p> <p>13 A. I'm not sure. She was employed by CMS</p> <p>14 around that time, but I don't know exactly when she</p> <p>15 started.</p> <p>16 Q. And Mr. Rodler I understand was somebody</p> <p>17 who had been at HCFA and the Medicaid Bureau prior</p> <p>18 to you being there?</p> <p>19 A. Correct.</p> <p>20 Q. And then at some point he retired or</p> <p>21 moved on?</p> <p>22 A. Correct.</p>
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<p>1 MR. TORBORG: And those are ones that</p> <p>2 you're working on currently and we intend to</p> <p>3 schedule a second day with Ms. Gaston so that we can</p> <p>4 go over those documents.</p> <p>5 MS. MARTINEZ: I believe what you told me</p> <p>6 is that you'd look at them and see if you need an</p> <p>7 additional day.</p> <p>8 MR. TORBORG: That's true.</p> <p>9 MS. MARTINEZ: But naturally --</p> <p>10 MR. TORBORG: I will need an additional</p> <p>11 day anyway.</p> <p>12 MS. MARTINEZ: Okay. That's what I</p> <p>13 thought.</p> <p>14 MR. TORBORG: Okay.</p> <p>15 BY MR. TORBORG:</p> <p>16 Q. Okay. Going back to the subject of</p> <p>17 federal upper limits, Ms. Gaston, I want to ask just</p> <p>18 a few very general background questions about how</p> <p>19 the process worked at HCFA, who was involved in what</p> <p>20 aspects and things of that nature. Earlier you</p> <p>21 testified or you identified three people at CMS who</p> <p>22 were involved in establishing the FULs. I believe</p>	<p>1 Q. Do you know when he retired or moved on?</p> <p>2 A. No.</p> <p>3 Q. Can you give me a sense? Was it early</p> <p>4 '90s, late '80s?</p> <p>5 A. I'm guessing it was in the '90s. Not in</p> <p>6 the late '90s, but I'm not sure.</p> <p>7 Q. And Cindy Bergin, when did she work at</p> <p>8 CMS on the FUL issues?</p> <p>9 A. She was hired -- I'm not sure exactly the</p> <p>10 date -- probably eight or nine years ago. And I</p> <p>11 mentored here on the FULs until I left in 2003.</p> <p>12 Q. So she would have been someone that was</p> <p>13 working on FUL issues starting in the mid to late</p> <p>14 '90s; is that fair to say?</p> <p>15 A. That's fair to say.</p> <p>16 Q. And did you work with Mr. Rodler on the</p> <p>17 federal upper limit issues or did you sort of</p> <p>18 succeed his duties?</p> <p>19 A. He taught me how to handle the federal</p> <p>20 upper limit program. And then when he left I took</p> <p>21 it over.</p> <p>22 Q. And did Cindy Bergin take it over from</p>

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1 you --
 2 A. Yes.
 3 Q. And then at some point is it your
 4 understanding that Gail Sexton took it over from
 5 Cindy Bergin or were they both working on it?
 6 A. She -- Cindy trained Gail and then Gail
 7 took it over when Cindy left the area.
 8 Q. So it sounds to me -- and please tell me
 9 if I'm mischaracterizing this or misunderstanding
 10 this -- that the mechanics of the FUL program were
 11 handled primarily by one person, but there was some
 12 overlap in training. Is that right?
 13 MS. MARTINEZ: Objection, form.
 14 A. Generally speaking. There were periods
 15 when it was just one person. And then when there
 16 were two, even though one was training they were
 17 both working on it.
 18 Q. And did you first get involved -- is it
 19 your recollection that a transition between yourself
 20 and Mr. Rodler happened in the early '90s; is that
 21 fair to say?
 22 A. When Pete retired then I took it over.

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1 Q. And was there anyone else working on the
 2 FUL issues besides yourself from that point until
 3 Cindy Bergin came on in the mid to late '90s?
 4 A. There was a period of time where I
 5 trained Altamease Arnold, but --
 6 Q. Was she in your office?
 7 A. She was in our office. But she was
 8 never -- she never really worked on the program per
 9 se.
 10 Q. When you say per se, what do you mean by
 11 that? Officially or what does that mean?
 12 A. She never really learned the program to
 13 work on it.
 14 Q. What does it mean to learn the program?
 15 A. When you try to teach someone the program
 16 but they choose not to absorb what you're teaching.
 17 Q. Got it. Is she still working at CMS?
 18 A. No.
 19 Q. When did she leave CMS?
 20 A. She retired last year.
 21 Q. What was her position at CMS?
 22 A. Health insurance specialist.

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1 Q. Was that the same position that you had?
 2 A. Yes.
 3 Q. So you were equals, so to speak?
 4 A. Most of the analysts in our area are all
 5 health insurance specialists.
 6 Q. Okay. And you indicated that Mr. Reed
 7 would have some input into the FULs and I think you
 8 used the word even the final say.
 9 A. Correct.
 10 Q. What does that mean?
 11 A. He's the division director.
 12 Q. So what would the extent of his
 13 involvement be with FULs? When would he get
 14 involved?
 15 A. Throughout -- whenever necessary he was
 16 there to discuss issues that might need to be
 17 discussed. The final publication he was aware of
 18 and would have to give his okay in order to send it
 19 through or any letters that would go through
 20 generally were from an authority higher than me.
 21 Q. Can you tell me what kind of issues would
 22 come up in the FUL program that would necessitate

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1 his involvement?
 2 A. Maybe just general discussion.
 3 Especially when I was the only one working on the
 4 FUL program, just a general discussion of maybe
 5 particular drugs, the pricing just somebody to have
 6 an open discussion about how we're setting the
 7 prices, because there's manual review involved.
 8 Q. What do you mean when you say there's
 9 manual review involved? And we'll get into a little
 10 bit more the mechanics, but generally speaking what
 11 do you mean by that?
 12 A. Generally you have paper that you work
 13 from. You have the compendia with all the drug
 14 numbers on it and the pricing. And sometimes you
 15 have to make determinations if it looks like a drug
 16 is truly available or not, whether you should follow
 17 up and see if it's available. Sometimes it's better
 18 to discuss it with someone to see that you're
 19 looking at it the same way that they might be
 20 looking at it.
 21 Q. When you say truly available, do you
 22 remember is the product available from a particular

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<p style="text-align: right;">Page 230</p> <p>1 manufacturer, whether it be because they quit making 2 the drug or they have a shortage of the drug? Is 3 that what you're talking about? 4 A. I think what I'm talking about, at least 5 preliminarily, is we have printouts from the 6 compendia. And just looking at the printouts, 7 sometimes there might be pricing that looks like 8 it's not updated in the compendia source. So you 9 might want to discuss and say does this look like 10 it's maybe old pricing, maybe we should follow up 11 and see if it's still available. Has the pricing 12 been updated, is the drug still out there, because a 13 lot of times the compendia might not be totally up 14 to date. 15 Q. How much of your time, if you could 16 estimate, in your position as a health insurance 17 specialist from '91 to 2003, roughly, did you spend 18 on the FUL program? 19 A. I really can't say. There was a period 20 of time when we were trying to get a publication out 21 where I could spend the majority of my time working 22 on it. I had other duties, so the FULs couldn't</p>	<p style="text-align: right;">Page 232</p> <p>1 902-0446. Ms. Gaston, if you would take a look at 2 that document and let me know if that's a document 3 that you're familiar with. 4 A. Yes. I am familiar with it. 5 Q. Could you tell us what this document is? 6 A. It looks like it's just an overview of 7 the federal upper limit program. 8 Q. Did you play a part in drafting this 9 document? 10 A. I may have. I'm not sure. 11 Q. Ms. Gaston, can you walk me through 12 basically what you did to establish federal upper 13 limits for drugs? Can you just walk me through the 14 process? 15 A. Do you want me to use this exhibit? 16 Q. If it helps -- 17 A. Okay. 18 Q. -- that would be fine. I'm just trying 19 to have you -- put me back in your office back in 20 the mid-'90s or whenever you were working on this 21 and tell me what you did. 22 A. Well, first of all we have an</p>
<p style="text-align: right;">Page 231</p> <p>1 take up all of my time every day. It just depended 2 on what activity occurred. You would stop. You 3 would work on the FULs. Then I would go back to my 4 other areas. 5 Q. Did you work -- are you a five-day 6 employee every week or did you work part time during 7 this time? 8 A. During the 2003 -- 9 Q. During the '91 through 2003 time period? 10 A. I was an eight hour a day, five day -- 11 Q. Five day a week employee? 12 A. Correct. 13 Q. All right. Could you walk me through 14 the -- let me see if it helps facilitate the 15 discussion to find a document here that might help 16 us talk about this a bit. 17 (Exhibit Abbott 462 was 18 marked for 19 identification.) 20 BY MR. TORBORG: 21 Q. For the record, what I've marked as 22 Abbott Exhibit 462 bears the Bates numbers HHC</p>	<p style="text-align: right;">Page 233</p> <p>1 application. I'm going to talk about it in 2 reference to the application that's used that houses 3 this information. But our systems folks when it's 4 time to set a FUL or put out a new list of FUL 5 drugs, the system folks will obtain the FDA Orange 6 Book data and they'll pull that into their system. 7 And there are some standards within that program 8 that look for the criteria that's sort of detailed 9 in this handout here. 10 Once that criteria is met then the system 11 will pull in the latest compendia data and then 12 they'll merge the two. And the compendia data, 13 there's some criteria in there too. But they try to 14 match the compendia data to the drugs pulled from 15 the FDA. And they match them together and then the 16 application -- and I'm simplifying this -- but the 17 application will have in there FUL groups, which 18 include like all NDC numbers, and it will have the 19 FUL group, the drug names, the NDC number and then 20 the compendia and the compendia pricing in there. 21 So it will have the source, if it's Red 22 Book, Blue Book, Medi-Span, and then it will have</p>

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1 the prices. It will have an AWP price, a direct
 2 price or WAC price. If there's not a price it'll
 3 just be blank in any of those categories. And then
 4 the system, the application itself -- from my
 5 recollection -- it's been a while since I've used
 6 it. But it will determine a FUL price where it can.
 7 Then we apply some manual review just to
 8 assure we have -- there's some edits and I can't
 9 remember all of those. But we want to make sure
 10 that it's using -- because it's supposed to use the
 11 lowest price in published compendia, and we want to
 12 make sure that that lowest price is a true price,
 13 that it's using a true price to establish a FUL.
 14 So there's a manual review that's applied
 15 to some of the drugs where the pricing might not
 16 look right in there or there's missing pricing. But
 17 basically there's a lot of manual review that's
 18 included before the final FUL listing will come out.
 19 Q. Okay. I appreciate that. I'm going to
 20 try to follow up on each of those steps as best I
 21 can. You indicated that there was a system
 22 involved.

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1 A. It's an application.
 2 Q. I think I've seen some documents that
 3 indicate the FUL process was computerized?
 4 A. Correct.
 5 Q. Right? Is that what you're talking about
 6 when you talk about the system?
 7 A. Yeah. It's an application that they use.
 8 Q. And what kind of application is it?
 9 A. I'm not a techie person. I don't know.
 10 It's on the computer. It's an application. I don't
 11 know what more -- how to describe it.
 12 Q. Was the application set up before you
 13 started working on it or did you --
 14 A. No.
 15 Q. -- take part in setting it up?
 16 A. When I first started working on FULs it
 17 was in our mainframe. The activity would occur in
 18 our mainframe. They took it from the mainframe and
 19 put it into an application that they can use on the
 20 computer, if that helps.
 21 Q. And do you recall -- was there someone --
 22 you mentioned systems folks. Was there somebody at

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1 CMS in the systems department that was involved in
 2 this?
 3 A. In the switch to the new application?
 4 Q. Yeah. And basically the FUL program in
 5 general. Who was involved in loading data --
 6 A. The systems support was Dona Kaufman.
 7 D-o-n-a.
 8 Q. Was there anyone else you recall or was
 9 she the primary person?
 10 A. There was someone before her, but he no
 11 longer works for CMS and I can't remember his name.
 12 But she was the main one for the new application.
 13 Q. Do you know if she's still there today?
 14 A. Yes.
 15 Q. Do you recall when the new application --
 16 when you moved from the mainframe to the new
 17 application?
 18 A. Time?
 19 Q. Yes. When that happened.
 20 A. After '95.
 21 Q. Prior to 1995 was the process still
 22 computerized bringing in information from the

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1 compendia and that kind of information?
 2 A. It was brought into the mainframe.
 3 Q. Just brought into a different computer in
 4 other words? I'm not a techie either.
 5 A. I'm just saying mainframe because that's
 6 what I know.
 7 Q. And do you know what the application is
 8 called?
 9 A. FULs.
 10 Q. FULs. Now, the Orange Book has a place
 11 in this process, correct?
 12 A. Right.
 13 Q. And could you tell us what the Orange
 14 Book is and what impact it had?
 15 A. The FDA Orange Book. It lists the drugs
 16 that are grouped by the FDA. If you have an Orange
 17 Book available, I think they have on the front
 18 page -- yeah -- the Orange Book can explain it much
 19 better than I can. But -- yeah.
 20 Q. I'm handing you our only copy of the
 21 Orange Book.
 22 A. But they get this electronically and it

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<p>1 just has drugs by ingredient names. And they don't 2 have NDC numbers or anything in here. But they pull 3 data from the Orange Book where the criteria that's 4 in the regulation -- so it meets that criteria. And 5 they just pull what they can from there. There's 6 other type of system criteria in there that picks 7 the drugs that are selected for the FULs. But it 8 pulls it from the Orange Book first. 9 Q. So they have an electronic version of the 10 Orange Book? 11 A. They -- it's my understanding they do 12 now. 13 Q. Do you know when they first started using 14 an electronic version of the Orange Book versus some 15 other method of getting the Orange Book data into 16 this computer? 17 A. I really don't know. 18 Q. Do you recall at some point somebody had 19 to go through the manual copy of the Orange Book -- 20 A. Oh, no. They wouldn't go through the 21 manual. They would just request the data from FDA. 22 I think the data now is available and they could go</p>	<p>1 products approved by the FDA are A-rated which are 2 therapeutically equivalent and then there must be 3 two rated A in the Orange Book. And then there's 4 another criteria where they can also allow a B-rated 5 drug when the A-rated drug products -- when there's 6 three A-rated drug products in the Orange Book. 7 Q. Okay. So if not all the drugs within a 8 drug product group are rated A, then you have to 9 have three that are rated A? 10 A. Correct, to allow a B-rated product. 11 Q. Now, would the B-rated product or a 12 product that's not rated A, would that still be 13 governed by the FUL? 14 A. If it's included in this, yes. 15 Q. What involvement would you have in the 16 review of the Orange Book data and what gets on the 17 Orange Book lists in the computer? 18 A. I have nothing to do with that. 19 Q. Who was involved in that? 20 A. If you're saying reviewing it -- 21 Q. Just who was involved in deciding which 22 drugs from the Orange Book, whether it be manual or</p>
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<p>1 on the Web or someplace in FDA's website and obtain 2 the data now. 3 Q. But it was all done to your knowledge -- 4 as far as you can recall it was done electronically 5 in some way? 6 A. Correct. 7 Q. Somebody would set up a program that 8 would, say, identify the drugs that meet the FUL 9 criteria and then down those into a file, something 10 called Orange Book or something like that? Is that 11 how it worked? 12 A. You would have to talk to our systems 13 folks. I just know that they would get -- they had 14 the criteria set in there and however it works, you 15 know. I mean, we're simplifying it, but I'm not a 16 data person. We just tell them what we need from 17 the Orange Book and they set up their criteria on 18 how they're going to get it and how it's selected. 19 Q. And do you recall what the criteria was 20 for a drug to qualify for the FUL program? 21 A. I'm going to read it from here. But it 22 says -- well, all the formulations of the drug</p>	<p>1 electronic, get put into your FUL computer? 2 A. The system folks would download the drugs 3 from the Orange Book. If further review is needed, 4 if some of the drugs are questionable, if they met 5 the criteria and maybe weren't on there before, then 6 we would look at those drugs to verify that they did 7 meet the criteria. 8 Q. Let me ask you a specific question here. 9 And I'll give you my copy of this. 10 MR. TORBORG: And Ms. Martinez, you can 11 look on with her if you'd like. 12 MS. MARTINEZ: I'm going to try to stay 13 away from that videotape. 14 THE WITNESS: Thanks. 15 BY MR. TORBORG: 16 Q. Specifically, on this top page, the right 17 column is a drug under the prescription drug product 18 list by the name vancomycin hydrochloride. 19 MS. MARTINEZ: Give me one second just to 20 glance at what it is. 21 Counsel, would you like to lay out a 22 little bit of foundation, like maybe the date of the</p>

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<p style="text-align: right;">Page 242</p> <p>1 book or something?</p> <p>2 MR. TORBORG: I think it's dated on the</p> <p>3 side 1996.</p> <p>4 MS. MARTINEZ: Right. I'm just saying</p> <p>5 for the record, we're not going to have an exhibit,</p> <p>6 so --</p> <p>7 MR. TORBORG: Sure. That's a good idea.</p> <p>8 I'll do that.</p> <p>9 BY MR. TORBORG:</p> <p>10 Q. Ms. Gaston, do you recognize that book?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Could you tell us what it is?</p> <p>13 A. It's the FDA Orange Book.</p> <p>14 Q. It's a hard copy version dated 1996?</p> <p>15 A. Correct.</p> <p>16 Q. And the FDA publishes its Orange Book</p> <p>17 once every year; is that right?</p> <p>18 A. I'm not sure.</p> <p>19 Q. Okay. In any event, this one at the side</p> <p>20 says it's 1996?</p> <p>21 A. Correct.</p> <p>22 Q. And is it your understanding that the</p>	<p style="text-align: right;">Page 244</p> <p>1 Q. Which manufacturers are there?</p> <p>2 MS. MARTINEZ: Excuse me. Just for the</p> <p>3 record, could we have -- again, since we have no</p> <p>4 exhibit, could we have the page that she's looking</p> <p>5 at, page number for the record?</p> <p>6 THE WITNESS: 3-302.</p> <p>7 A. Fujisawa, Lilly and I think that's it.</p> <p>8 Q. Can I take a look at that real quick?</p> <p>9 A. Mm-hmm.</p> <p>10 Q. Did you see one for Abbott?</p> <p>11 A. Oh, okay. You're over here too. It's</p> <p>12 also on page 3-303. Is this a continuation over</p> <p>13 here of this?</p> <p>14 Q. That's the way that I read it, but --</p> <p>15 MS. MARTINEZ: Since we can't see what --</p> <p>16 A. Okay. Ledderle, it looks like they're in</p> <p>17 here too. Abbott, Elkins. Okay. That's it.</p> <p>18 Q. Now, based on your understanding, are</p> <p>19 there any of those vancomycin products that are not</p> <p>20 rated A?</p> <p>21 A. It doesn't appear that way.</p> <p>22 Q. So under the regulatory and statutory</p>
<p style="text-align: right;">Page 243</p> <p>1 Orange Book has different sections, one of which is</p> <p>2 titled Product Drug Cost Listing or something like</p> <p>3 that? If you look at the top page there.</p> <p>4 A. Are you talking about in here? It's been</p> <p>5 years since we've I've looked at one of these books,</p> <p>6 so --</p> <p>7 Q. If you look at the spot that I showed</p> <p>8 you, where your finger is, what does the top of that</p> <p>9 say? I can't remember exactly.</p> <p>10 A. "Prescription drug product list."</p> <p>11 Q. Do you know what that means?</p> <p>12 A. Prescription drug product list.</p> <p>13 Q. So that's a list of prescription products</p> <p>14 in the Orange Book --</p> <p>15 A. Okay.</p> <p>16 Q. -- by alphabetical order? Is that what</p> <p>17 it looks like?</p> <p>18 A. That's what it looks like.</p> <p>19 Q. And looking at vancomycin hydrochloride</p> <p>20 there, there are a number of different manufacturers</p> <p>21 listed; is that right?</p> <p>22 A. Correct.</p>	<p style="text-align: right;">Page 245</p> <p>1 criteria vancomycin hydrochloride would qualify as a</p> <p>2 drug product that would satisfy the FUL criteria; is</p> <p>3 that right?</p> <p>4 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>5 MS. MARTINEZ: Objection, form.</p> <p>6 A. I would say no, because -- just because</p> <p>7 it's A-rated. This is an injection.</p> <p>8 Q. Okay.</p> <p>9 A. So I don't know if this product -- if</p> <p>10 this is an injectable, then there are certain</p> <p>11 products that are in the included on the FUL.</p> <p>12 Q. And we'll talk about that in a bit. Why</p> <p>13 don't we talk about it now. Why are not injectable</p> <p>14 products included on the FUL?</p> <p>15 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>16 A. When I started to work on the FULs</p> <p>17 injectable products were not included. And it's my</p> <p>18 understanding that the purpose of the FUL program is</p> <p>19 to set reimbursement rates on drugs that are</p> <p>20 generally used by the Medicaid population in an</p> <p>21 outpatient-type, like a pharmacy-type setting, most</p> <p>22 commonly used products. And it's my understanding</p>

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<p style="text-align: right;">Page 246</p> <p>1 that injectables and other products many times are 2 provided in a physician's office and other type of 3 settings where they might not be claimed separately. 4 They might be included in a payment, like a 5 physician payment. 6 Also, injectables, many times when 7 they're billed on the claim form they're not -- 8 they're billed with codes rather than NDC numbers, 9 which means that the states may not be paying for 10 them through their pharmacy benefit but through 11 another means, such as a physician's visit or a 12 hospital or something like that. 13 So many times what we're trying to do 14 with the FULs is use most commonly used drugs and 15 covered outpatient drug type, so like tablets and 16 capsules. 17 Q. Is there anything in the regulations or 18 statutes that limit the FUL program to tablets or 19 capsules or other drugs that are commonly 20 administered in the outpatient setting? 21 A. Not that I know of. 22 Q. That was just the -- when you started</p>	<p style="text-align: right;">Page 248</p> <p>1 Q. Because if the initial identification of 2 drugs that satisfied the criteria was just two or 3 more A-rated drugs or three or more A-rated drugs if 4 one of them was not A-rated, and that was done by 5 computer presumably that would bring in injectable 6 drugs like vancomycin, right? 7 MS. ALBEE: Objection. 8 A. No. There are still more criteria. You 9 still have the Orange Book criteria, but there are 10 still criteria that the systems folks put in to look 11 for the type of drugs that the FUL prices are set 12 on. 13 Q. So is it your understanding that HCFA 14 specifically set up the computer program to identify 15 and exclude injectable drugs? 16 MS. MARTINEZ: Objection, form. 17 A. In one part of the process, yes. 18 Q. And do you know in what part of the 19 process that was done? 20 A. No, I don't. 21 Q. Did you have any part in that process of 22 either manually excluding the injectables drugs or</p>
<p style="text-align: right;">Page 247</p> <p>1 working on the FULs that was just the way that HCFA 2 approached it, you did not establish FULs on the 3 injectables? 4 A. Correct. 5 Q. And did you ever receive any explanation 6 about why that was? 7 A. I can't say specifically there was an 8 explanation. I think you learn this as you work 9 with the program. 10 Q. But you would agree with me that the 11 Orange Book page that I showed you does show that in 12 1996 there were at least two versions of vancomycin 13 that were rated A in the Orange Book? 14 A. Correct. 15 MS. MARTINEZ: Objection, form. 16 Q. And so -- I want to get back to this 17 computer business. Was the computer program 18 specifically designed to not include injectables or 19 how did that work? 20 A. You'd have to talk to the data folks. We 21 were not including injectables. I don't know what 22 criteria they put in there.</p>	<p style="text-align: right;">Page 249</p> <p>1 setting up a computer program such that those drugs 2 would be moved aside? 3 A. The basic criteria for the system was 4 developed before I got there. 5 Q. Who would be the best person to ask about 6 why it was that injectables were specifically 7 excluded from the FUL program? 8 MR. WINGET-HERNANDEZ: Objection, form. 9 MS. MARTINEZ: Objection, form. 10 A. I don't know. Pete Rodler was the first 11 one I know that worked on FULs. That's the only 12 person I could think of. 13 Q. Are these other -- now, we've talked a 14 little bit about Exhibit 462 that talks about the 15 Orange Book data. And we talked about the criteria 16 already, correct? And now you've identified I think 17 another criteria, which is to exclude injectable 18 drugs, right? 19 MS. MARTINEZ: Objection, form. 20 A. Correct. 21 Q. Is that criteria written down anywhere? 22 MR. WINGET-HERNANDEZ: Objection, form.</p>

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<p>1 A. I don't know.</p> <p>2 Q. Have you ever seen a policy memorandum or</p> <p>3 any other memorandum that discusses why injectables</p> <p>4 are specifically excluded from the FUL program?</p> <p>5 MS. MARTINEZ: Objection, form.</p> <p>6 A. I'm not aware of that.</p> <p>7 Q. Are you aware of any other criteria that</p> <p>8 HCFA has used to eliminate drugs that might</p> <p>9 otherwise satisfy the regulatory or statutory</p> <p>10 criteria?</p> <p>11 A. I think unit dose.</p> <p>12 Q. Can you explain a little bit -- that unit</p> <p>13 stuff always makes my head spin.</p> <p>14 A. Just the little individual unit dose</p> <p>15 packets, like little individual blister tablets that</p> <p>16 might be in the little blister pack that are</p> <p>17 generally distributed within a hospital setting.</p> <p>18 Q. And why are those -- do you understand</p> <p>19 why those are excluded?</p> <p>20 A. Here again, what I think they're trying</p> <p>21 to focus on is what's the drugs that are commonly</p> <p>22 used and dispensed by the pharmacies.</p>	<p>1 Q. Any other criteria you're aware of?</p> <p>2 A. That's all I can think of.</p> <p>3 Q. And do you know if the blister pack or</p> <p>4 the infusion bag exclusions are written down</p> <p>5 anywhere?</p> <p>6 A. I'm not aware of that.</p> <p>7 Q. Are -- I'm sorry.</p> <p>8 A. The systems folks, they might have</p> <p>9 written criteria. I really don't know and I can't</p> <p>10 speak for them. But I'm not aware of any.</p> <p>11 Q. Do you recall any discussions about --</p> <p>12 apart here today in the deposition, of course --</p> <p>13 about why infusion bags, blister packs and</p> <p>14 injectable drugs are not included in the FUL list?</p> <p>15 A. You mean specific discussions?</p> <p>16 Q. Or general discussions. Anything you</p> <p>17 recall.</p> <p>18 A. I'm sure that it was discussed over the</p> <p>19 years just within the process of working on the</p> <p>20 FULs.</p> <p>21 Q. Do you know if HCFA has since changed the</p> <p>22 way that it does FULs so that any of those three</p>
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<p>1 Q. Any other exclusion criteria that you're</p> <p>2 aware of?</p> <p>3 A. They may not want to capture the infusion</p> <p>4 bags because here again that's generally used in an</p> <p>5 impatient setting and not dispensed at the pharmacy.</p> <p>6 Q. Do you know if that's the fact that the</p> <p>7 FUL program does not cover infusion bags? Is that</p> <p>8 something that you're aware of?</p> <p>9 A. As far as I know they don't.</p> <p>10 Q. And infusion bags would be what type of</p> <p>11 products?</p> <p>12 A. I really can't say at this point.</p> <p>13 Q. Saline solution?</p> <p>14 A. Okay, fine.</p> <p>15 Q. Is that one?</p> <p>16 A. Yeah.</p> <p>17 Q. Dextrose-type solutions?</p> <p>18 A. That's my understanding.</p> <p>19 Q. And the rationale for exclusion of those</p> <p>20 is the same as the rationale for excluding the</p> <p>21 injectable drugs?</p> <p>22 A. Correct.</p>	<p>1 categories' exclusions are no longer excluded?</p> <p>2 A. I have no idea.</p> <p>3 Q. Okay. I think that the next step you</p> <p>4 discussed was the pulling in of the compendia</p> <p>5 data --</p> <p>6 A. Correct.</p> <p>7 Q. -- into the mainframe or later the</p> <p>8 application, correct?</p> <p>9 A. Correct.</p> <p>10 Q. And was that done with electronic copies</p> <p>11 of the compendia data?</p> <p>12 A. I don't know. I don't know how they</p> <p>13 obtained that data. I would assume it's electronic,</p> <p>14 but I don't know.</p> <p>15 Q. But you did not sit down with a copy of</p> <p>16 the Red Book or the Blue Book, a manual copy, and</p> <p>17 input things into a computer?</p> <p>18 A. No.</p> <p>19 Q. Right? What you know is that by the time</p> <p>20 you got involved somebody had already loaded the</p> <p>21 data into the system?</p> <p>22 A. Correct.</p>

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<p>1 Q. Is that fair to say?</p> <p>2 A. Yup.</p> <p>3 Q. Do you know which compendia they used?</p> <p>4 A. Red Book, Blue Book and Medi-Span.</p> <p>5 Q. They Would use all three?</p> <p>6 A. Correct.</p> <p>7 Q. Do you know if they used all three from</p> <p>8 1991 when you got involved through 2003?</p> <p>9 A. I can't remember. I know there was a</p> <p>10 time when I think Medi-Span and First Databank might</p> <p>11 have merged. But I would still -- from my</p> <p>12 recollection I think there was still separate</p> <p>13 pricing under both of them. So from my recollection</p> <p>14 it was always three.</p> <p>15 Q. Did you have a hard copy of the Red Book</p> <p>16 or the Blue Book on your desk or in your cubicle?</p> <p>17 A. Red Book I would have a copy. Just</p> <p>18 their -- I think it's a monthly publication.</p> <p>19 Q. Did you have a copy of the Orange Book?</p> <p>20 A. At times.</p> <p>21 Q. And then -- so you've got the Orange Book</p> <p>22 data loaded. Is it fair to say that that's in one</p>	<p>1 were -- I can't remember exactly, but there were</p> <p>2 certain drug groups that might show up that need to</p> <p>3 be manually looked at because there might not be</p> <p>4 enough suppliers or there might not be enough</p> <p>5 pricing. And I can't remember what else might be</p> <p>6 said in there.</p> <p>7 But we would go through. And then when</p> <p>8 instances like that would occur that what we would</p> <p>9 do is sometimes print off that information and then</p> <p>10 research to see if the information in the compendia</p> <p>11 was incorrect or if it is correct then we can sort</p> <p>12 of go in there and work with what -- you know, try</p> <p>13 to make a decision whether it should be included or</p> <p>14 not.</p> <p>15 Q. How did you become aware of potential</p> <p>16 issues that may arise? Did people contact you and</p> <p>17 you looked at things in response to their concerns</p> <p>18 or was there a methodology that you followed to spot</p> <p>19 issues?</p> <p>20 MS. MARTINEZ: Objection, form.</p> <p>21 A. Are you asking me -- when you say</p> <p>22 potential issues, you mean raised by individuals</p>
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<p>1 file or one spot on the computer but then you've got</p> <p>2 the compendia data loaded in another spot?</p> <p>3 A. I can't speak for the systems aspect of</p> <p>4 it. We just -- we see it -- in the application we</p> <p>5 see the end result of the Orange Book and the</p> <p>6 compendia merged together.</p> <p>7 Q. Okay. So there's a program that merges</p> <p>8 the two together and automatically identifies drugs</p> <p>9 that meet the Orange Book criteria, any other</p> <p>10 criteria we've discussed and also have available</p> <p>11 information in the compendia data; is that right?</p> <p>12 A. Correct.</p> <p>13 Q. And that's when you get involved; is that</p> <p>14 fair to say?</p> <p>15 A. Correct.</p> <p>16 Q. You don't get involved before that?</p> <p>17 A. Correct.</p> <p>18 Q. Can you take me from that point in time</p> <p>19 through the publication of the FUL list to the</p> <p>20 public?</p> <p>21 A. From what I remember what we would do is</p> <p>22 just go through the various groups. I think there</p>	<p>1 or -- I don't know when you mean by potential</p> <p>2 issues.</p> <p>3 Q. Well, we talked about there was a manual</p> <p>4 review of this. You wouldn't just take whatever the</p> <p>5 computer spat out and make that the FUL list?</p> <p>6 A. Correct.</p> <p>7 Q. There was a manual review involved to</p> <p>8 identify some issues. I think you've talked about</p> <p>9 some of them here today. Availability of the drug,</p> <p>10 whether the pricing information was still correct.</p> <p>11 Any other issues that you recall?</p> <p>12 A. They are the two main ones, yeah.</p> <p>13 Q. How would you go about identifying those</p> <p>14 issues? Like how do you -- there's a lot of drugs</p> <p>15 on the FUL list. How would you go about figuring</p> <p>16 that stuff out?</p> <p>17 A. I can't remember exactly, because I</p> <p>18 haven't dealt with the application for years. But</p> <p>19 there was something in the application that would</p> <p>20 alert us to certain drugs that needed the manual</p> <p>21 review. Maybe it was the fact that the system</p> <p>22 couldn't come up with a price because something</p>

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<p>1 wasn't right in the application itself, something 2 didn't look right, so then we would have to go 3 through and verify the information that we had in 4 our system. 5 Q. The computer system that did this was all 6 housed within HCFA? 7 A. CMS. 8 Q. It's CMS. 9 A. Yes. 10 Q. And then the computer program would 11 select the lowest price of the reported prices in 12 there and then would it multiply it by 150 percent 13 and spit out a price? 14 A. Correct. 15 Q. And which prices in the compendia would 16 be included in that analysis that the computer did? 17 A. Are you saying from the compendia 18 sources? 19 Q. Yes. Average wholesale price? 20 A. Average wholesale price, direct price, 21 wholesale acquisition cost. 22 Q. Are there any other prices that you're</p>	<p>1 last page mean? 2 A. That was the document where it was 3 saved -- well, that I prepared it. The FME was our 4 identification. And then it has the typist and the 5 disk that the typist placed it on. 6 Q. What does FME 32 mean? 7 A. I'm not sure. 8 Q. What does the 60488 number mean? 9 A. My extension. 10 Q. Your phone number? 11 A. Yes. 12 Q. So this indicates that you were the one 13 that prepared this memorandum? 14 A. Correct. 15 Q. The second paragraph -- let me ask you 16 also, if I could, the chart at the bottom of the 17 first page of this document, that little box next to 18 file copy, what does this mean? 19 A. It's a sign-off for correspondence. 20 Q. So your name is first. That means I 21 guess you were the first one involved? Is that what 22 that means?</p>
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<p>1 aware of? 2 A. Not that I remember. 3 Q. But the computer did all that and then 4 you came in and looked at some issues afterwards, 5 correct? 6 A. Correct. 7 MR. WINGET-HERNANDEZ: Objection, form. 8 Q. Okay. I handed you before Abbott 9 exhibit -- I forget the number of it. It was a 10 document that has a handwritten notation at the top, 11 September 15, 1993. Do you see that? 12 A. 461? 13 Q. 461, yes. 14 And I note that your name is listed at 15 the bottom of the document in a chart as well as at 16 the end of the document. There's something that 17 says at Bates page 858, FME 32, Sue Gaston, 60488. 18 A. Right. 19 Q. Let me ask you first if you remember this 20 document? 21 A. It looks familiar. 22 Q. And what does that information on the</p>	<p>1 A. Well, I was the one -- I prepared this, 2 the document. Larry Reed approved it. 3 Q. And then there's another name after that 4 which I can't read. 5 A. Yeah. I don't know who that is. 6 Q. And the last one is Abato. 7 A. Okay. 8 Q. Rozanne Abato; is that correct? 9 A. Correct. 10 Q. What was her position? 11 A. I don't know if we were Medicaid Bureau 12 then. But I think she was the director. And I'm 13 guessing at the title. 14 Q. The second paragraph of this document you 15 wrote "Section 1927(e)(1) and (4) of the act as 16 amended by OBRA '93 mandates that HCFA establish a 17 federal upper limit for multiple source drugs that 18 meet specific criteria." Do you see that? 19 A. Yes. 20 Q. What is the reference to the act? Is 21 that the Social Security Act? 22 A. Yes.</p>

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<p>1 Q. And OBRA '93, that would be referencing 2 what? 3 A. It's the Social Security Act. It amended 4 the Social Security Act, just like OBRA '90 5 established section 1927, OBRA '93 made amendments 6 to section 1927. 7 Q. OBRA was a statute passed by Congress? 8 A. Yes. 9 Q. Omnibus Reconciliation Act? 10 A. Correct. 11 MS. MARTINEZ: Maybe Omnibus Budget 12 Reconciliation Act? 13 MR. TORBORG: Did I not say that? 14 MS. MARTINEZ: It has OMB. 15 MR. TORBORG: Oh. I'm sorry. Omnibus 16 Budget Reconciliation Act. 17 BY MR. TORBORG: 18 Q. And was it your understanding that 19 Congress had mandated HCFA to establish federal 20 upper limits for any multiple source drugs that met 21 specific criteria? 22 MS. MARTINEZ: Objection, form.</p>	<p>1 Q. Let me explain what this document is. 2 This is a section of the Omnibus Budget 3 Reconciliation Act of 1990. And I've included a 4 cover page which has the title as well as a section 5 4401 titled Reimbursement of Prescribed Drugs. 6 That's what this is. I have not given you the 7 entire OBRA 1990. 8 I'd like you, if you would, to go eight 9 more pages from the page you're at now. I'm sorry 10 it doesn't have page numbers on this. But it would 11 be a section F, pharmacy reimbursement. Were you 12 able to find it? 13 A. Yes. 14 Q. And under section 2 it says establishment 15 of upper payment limits. Do you see that? 16 A. Yes. 17 Q. And then it says "HCFA shall establish a 18 federal upper reimbursement limit for each multiple 19 source drug for which the FDA has rated three or 20 more products therapeutically equivalent and 21 pharmaceutically equivalent, regardless of whether 22 all such additional formulations are rated as such</p>
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<p>1 Q. Right? 2 A. Correct. 3 Q. Congress had told HCFA you must do this? 4 MS. MARTINEZ: Objection, form. 5 Q. Is that right? 6 A. Congress amended the law to include this. 7 Q. But the mandates means that HCFA was 8 mandated by law to establish federal upper limits 9 for multiple source drugs that met specified 10 criteria, correct? 11 MS. MARTINEZ: Objection to form. 12 A. If that's what the legislation does, yes. 13 Q. Have you ever reviewed the legislation? 14 A. What do you mean reviewed? 15 Q. Have you looked at it? 16 A. Yes. 17 Q. The actual statute itself? 18 A. Yes. 19 (Exhibit Abbott 463 was 20 marked for 21 identification.) 22 BY MR. TORBORG:</p>	<p>1 and shall use only such formulations when 2 determining any such upper limit." Do you recall 3 reviewing this language before? 4 A. Yes. 5 Q. Now, this statutory criteria does not 6 discuss any criteria relating to injection drugs or 7 infusion drugs; is that right? 8 A. It doesn't specify any drugs in 9 particular. 10 Q. It just says "all multiple source drugs 11 for which the FDA has rated three or more products 12 therapeutically and pharmaceutically equivalent," 13 correct? 14 MR. WINGET-HERNANDEZ: Objection to form. 15 You've misread it, Counsel. 16 MR. TORBORG: I'm sorry. I'll read it 17 again. 18 BY MR. TORBORG: 19 Q. "HCFA shall establish a federal upper 20 reimbursement limit for each multiple source drug 21 for which the FDA has rated three or more products 22 therapeutically and pharmaceutically equivalent."</p>

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<p style="text-align: right;">Page 266</p> <p>1 Did I read that right?</p> <p>2 A. Yes, you did.</p> <p>3 Q. Now, this indicates that HCFA shall</p> <p>4 establish it for each multiple source drug. And I</p> <p>5 think we saw earlier in looking at a copy of the</p> <p>6 1996 Orange Book that for vancomycin there were</p> <p>7 three or more drugs that were therapeutically and</p> <p>8 pharmaceutically equivalent, correct?</p> <p>9 MS. MARTINEZ: Objection to form.</p> <p>10 A. Correct.</p> <p>11 Q. And you indicated that if that was an</p> <p>12 injection drug it would not have met the -- it would</p> <p>13 have been knocked out of the FUL process by the</p> <p>14 computer; is that right?</p> <p>15 A. Correct.</p> <p>16 Q. And is that consistent with the statutory</p> <p>17 language here?</p> <p>18 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>19 MS. MARTINEZ: Objection, form.</p> <p>20 A. The language doesn't go into that type of</p> <p>21 detail in the statute.</p> <p>22 Q. It doesn't talk about excluding injection</p>	<p style="text-align: right;">Page 268</p> <p>1 end today? We've been going for I think an hour or</p> <p>2 more. I could continue to go until 5:00 if people</p> <p>3 want to stop at 5:00. And that's what I would</p> <p>4 recommend that we do, go another 25 minutes. Or</p> <p>5 since we started a little bit late, if people want</p> <p>6 to go past 5:00 I could take a break now.</p> <p>7 MR. WINGET-HERNANDEZ: I would prefer to</p> <p>8 go to 5:00 for what it's worth.</p> <p>9 MR. TORBORG: I think that probably makes</p> <p>10 more sense.</p> <p>11 MS. MARTINEZ: Yeah. I vote for going to</p> <p>12 5:00 and stopping, cutting out the break if</p> <p>13 everybody can take it.</p> <p>14 THE WITNESS: That's fine.</p> <p>15 MR. TORBORG: Is that okay?</p> <p>16 THE WITNESS: Mm-hmm.</p> <p>17 MR. TORBORG: Okay.</p> <p>18 THE VIDEOGRAPHER: I have 25 minutes</p> <p>19 remaining.</p> <p>20 MR. WINGET-HERNANDEZ: That's enough.</p> <p>21 That takes us to 5:00.</p> <p>22 MR. TORBORG: That will be perfect. All</p>
<p style="text-align: right;">Page 267</p> <p>1 or infusion drugs, does it?</p> <p>2 A. No, it doesn't.</p> <p>3 Q. Do you recall any discussions about that</p> <p>4 issue while you were at HCFA, whether or not the</p> <p>5 statutory or regulations governing the federal upper</p> <p>6 limit allowed HCFA to exclude injectable or infusion</p> <p>7 drugs?</p> <p>8 A. I don't -- no. I don't remember specific</p> <p>9 discussions like that.</p> <p>10 Q. You just know that for as long as you've</p> <p>11 been working on it it's just been something that's</p> <p>12 been excluded at the outset?</p> <p>13 A. Exactly. Yes.</p> <p>14 Q. And you have some understanding of why</p> <p>15 that is, but you weren't there originally when the</p> <p>16 decision was made?</p> <p>17 A. Correct.</p> <p>18 Q. You've just been told about this</p> <p>19 rationale over time?</p> <p>20 A. Right. I understand the rationale. It's</p> <p>21 been explained to me.</p> <p>22 MR. TORBORG: What time do people want to</p>	<p style="text-align: right;">Page 269</p> <p>1 things are coalescing into a decision to go.</p> <p>2 MS. MARTINEZ: Counsel, could I just</p> <p>3 request that at some point you make a copy of the</p> <p>4 pages that the witness looked at in the FDA drug</p> <p>5 book and we can just --</p> <p>6 MR. TORBORG: Mark it as an exhibit</p> <p>7 maybe?</p> <p>8 MS. MARTINEZ: Well --</p> <p>9 MR. TORBORG: Let's talk about it and</p> <p>10 deal with it at the end of the deposition.</p> <p>11 MS. MARTINEZ: Yeah. But if you could</p> <p>12 PDF that or something.</p> <p>13 MR. TORBORG: Yes.</p> <p>14 BY MR. TORBORG:</p> <p>15 Q. Now, is it your understanding that the</p> <p>16 federal regulations for FULs had an aggregate test?</p> <p>17 Do you understand what I mean by that?</p> <p>18 A. I do. The test part confuses me.</p> <p>19 Q. The states' compliance with federal upper</p> <p>20 limits was measured in the aggregate, correct?</p> <p>21 A. Yes. Correct.</p> <p>22 Q. Could you explain to us as best you can</p>

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<p style="text-align: right;">Page 270</p> <p>1 in plain English what that means?</p> <p>2 A. The federal government sets prices on the</p> <p>3 federal upper limit drugs. And we release those</p> <p>4 prices to the states. The states have the</p> <p>5 flexibility to adjust those prices so that in the</p> <p>6 aggregate the same savings is achieved. So they can</p> <p>7 raise one price and lower another price. But they</p> <p>8 have to be able to validate doing that.</p> <p>9 Q. And what types of auditing does HCFA do</p> <p>10 on the states' compliance with federal upper limits?</p> <p>11 MS. MARTINEZ: Objection, form.</p> <p>12 A. I'm not familiar with CMS's auditing.</p> <p>13 Q. You don't recall yourself doing any work</p> <p>14 to see if states were actually complying with the</p> <p>15 FUL regulations; is that fair to say?</p> <p>16 A. Correct.</p> <p>17 Q. Your involvement with the FULs was to</p> <p>18 take the primary lead in getting the list published</p> <p>19 in the first instance, but not necessarily -- or not</p> <p>20 at all with dealing with whether or not the states</p> <p>21 complied with the limits?</p> <p>22 MS. MARTINEZ: Objection to form.</p>	<p style="text-align: right;">Page 272</p> <p>1 This has been done for a variety of reasons. The</p> <p>2 most prevalent reason, however, is the discovery by</p> <p>3 the FDA that a specific manufacturer of a generic</p> <p>4 drug has not been totally accurate in its</p> <p>5 formulation of the drug.</p> <p>6 "When one of these inaccurately</p> <p>7 formulated generics is discovered, HCFA is required</p> <p>8 to remove all formulations of the generic from the</p> <p>9 upper limits listing, primarily due to problems in</p> <p>10 identifying the manufacturer of any particular</p> <p>11 generic item."</p> <p>12 Do you recall this issue at all?</p> <p>13 A. No, not at all.</p> <p>14 Q. Do you recall HCFA taking steps to</p> <p>15 affirmatively remove items from the federal upper</p> <p>16 limit list?</p> <p>17 A. During the period of time that I --</p> <p>18 Q. Yes.</p> <p>19 A. We would remove drugs if they didn't meet</p> <p>20 the criteria.</p> <p>21 Q. Apart from not meeting that statutory</p> <p>22 criteria, were there other reasons why drugs were</p>
<p style="text-align: right;">Page 271</p> <p>1 A. Correct.</p> <p>2 Q. Do you know anyone that was involved in</p> <p>3 doing that?</p> <p>4 A. No.</p> <p>5 MR. TORBORG: Okay. I'd like to mark</p> <p>6 this as our next exhibit, if we could.</p> <p>7 (Exhibit Abbott 464 was</p> <p>8 marked for</p> <p>9 identification.)</p> <p>10 BY MR. TORBORG:</p> <p>11 Q. For the record, what I've marked as</p> <p>12 Abbott Exhibit 464 bears the Bates numbers</p> <p>13 NYSHD-FOIL 01682 through 83, a document dated</p> <p>14 October 2nd 1990. I ask if you'd take a look at</p> <p>15 that, Ms. Gaston, and tell me whether or not you</p> <p>16 recall it.</p> <p>17 A. No. I've never seen this before.</p> <p>18 Q. Let me ask you some questions about some</p> <p>19 language in the document to see if you can help me</p> <p>20 understand some things. The second paragraph states</p> <p>21 "Over the past year, several state operations</p> <p>22 letters have been sent to you removing upper limits.</p>	<p style="text-align: right;">Page 273</p> <p>1 removed?</p> <p>2 A. No. I'm not aware of other reasons to</p> <p>3 remove them.</p> <p>4 Q. One other -- well, were there instances</p> <p>5 where you learned that there was an availability</p> <p>6 problem with the drug?</p> <p>7 A. Correct.</p> <p>8 Q. And in those instances would a FUL be</p> <p>9 removed?</p> <p>10 A. Yes. So that maybe I should clarify.</p> <p>11 When you said statutory, also regulatory and</p> <p>12 statutory. So --</p> <p>13 Q. Another background question I had was how</p> <p>14 were drugs -- was there a code that was used to</p> <p>15 group all generic drugs of the same type and dose</p> <p>16 into one category so those can be put together for</p> <p>17 establishing a FUL?</p> <p>18 A. We had FULs -- FUL groups.</p> <p>19 Q. FUL groups?</p> <p>20 A. Yeah. That's in the application. It</p> <p>21 would be a FUL group. But I can't go into exactly</p> <p>22 what my recollection of establishing those FUL</p>

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<p style="text-align: right;">Page 274</p> <p>1 groups. But that's what we would work with on the</p> <p>2 application, the FUL group, and then it would have</p> <p>3 all the NDC numbers and the compendia information.</p> <p>4 Q. Who established the FUL groups?</p> <p>5 A. It's in the system. The system</p> <p>6 establishes it.</p> <p>7 Q. Is it done electronically by a computer</p> <p>8 without any manual review?</p> <p>9 A. The information that's pulled down from</p> <p>10 the Orange Book in the compendia, once it's joined</p> <p>11 together it has to be placed into a FUL group in</p> <p>12 order to be into the application. Once it's in the</p> <p>13 application there may be some manual review</p> <p>14 required.</p> <p>15 Q. But the FUL groups were set up in the</p> <p>16 system and then drugs were taken from the Orange</p> <p>17 Book list and the compendia list and put together</p> <p>18 this FUL group list, right?</p> <p>19 A. Yeah.</p> <p>20 Q. And any FUL that was established for any</p> <p>21 FUL group would then limit the reimbursement that</p> <p>22 could be paid for any drug in that group; is that</p>	<p style="text-align: right;">Page 276</p> <p>1 recollection.</p> <p>2 Q. And what is the basic criteria?</p> <p>3 A. The criteria in the Orange Book that we</p> <p>4 discussed earlier and the criteria in the compendia</p> <p>5 for the suppliers.</p> <p>6 (Exhibit Abbott 465 was</p> <p>7 marked for</p> <p>8 identification.)</p> <p>9 BY MR. TORBORG:</p> <p>10 Q. Ms. Gaston, we've marked as Abbott</p> <p>11 Exhibit 465 a document bearing the Bates number HHC</p> <p>12 004-0054. It appears to be an e-mail from Cindy</p> <p>13 Pelter to a distribution that includes "C. Thomps,"</p> <p>14 which I believe is Cheryl Thompson, and an</p> <p>15 organization called the American Society of Health</p> <p>16 Systems Pharmacists. Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. If you could take a quick glance at that</p> <p>19 document and tell me whether or not you recall it.</p> <p>20 A. I don't recall it.</p> <p>21 Q. Who was Cindy Pelter?</p> <p>22 A. That's Cindy Bergin.</p>
<p style="text-align: right;">Page 275</p> <p>1 right?</p> <p>2 MS. MARTINEZ: Objection, form.</p> <p>3 Q. The FUL --</p> <p>4 A. It applies to a FUL group.</p> <p>5 Q. Yeah.</p> <p>6 A. Yes.</p> <p>7 Q. Okay.</p> <p>8 A. That's my recollection.</p> <p>9 Q. And it may be that the FUL would apply</p> <p>10 even if a particular drug was not rated A in Orange</p> <p>11 Book?</p> <p>12 A. As long as it met the basic criteria then</p> <p>13 that FUL price would apply to all of the drugs in</p> <p>14 that group.</p> <p>15 Q. And the drugs in the group, would those</p> <p>16 include drugs that were not rated A in Orange Book,</p> <p>17 do you know?</p> <p>18 A. Correct.</p> <p>19 Q. It would?</p> <p>20 A. It would be my understanding. As long as</p> <p>21 it meets the basic criteria, then all the other</p> <p>22 drugs would still be subject to the FUL. That's my</p>	<p style="text-align: right;">Page 277</p> <p>1 Q. That's Cindy Bergin?</p> <p>2 A. Yes.</p> <p>3 Q. That's what I suspected. That why I</p> <p>4 asked you earlier if she was still named -- what's</p> <p>5 her current name?</p> <p>6 A. You didn't ask me if she was still --</p> <p>7 Q. It's Cindy Pelter now?</p> <p>8 A. No. It's Cindy Bergin now. It's Bergin</p> <p>9 now. It was Pelter when she was hired. You're</p> <p>10 confusing me. This is the hardest question.</p> <p>11 Q. It's been a long day. Cindy Pelter is</p> <p>12 now Cindy Bergin?</p> <p>13 A. Correct.</p> <p>14 Q. And her name is spelled B-e-r-g-i-n?</p> <p>15 A. Correct.</p> <p>16 Q. I had that suspicion. And who is Cheryl</p> <p>17 Thompson? Do you know her?</p> <p>18 A. No.</p> <p>19 Q. Do you know what the American Society of</p> <p>20 Health Systems Pharmacists is?</p> <p>21 A. I'm really not familiar with them, no.</p> <p>22 Q. In any event, Cheryl Thompson asked</p>

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1 Ms. Pelter a question on June 19th that was "Do the
2 prices listed in" -- this release which I won't read
3 into the record -- "reflected information recently
4 provided by First Databank." Do you see that?
5 A. Right.
6 Q. And then she responds saying "No. The
7 new federal upper limit prices do not reflect the
8 new AWP prices recently published by First Databank.
9 Those new AWP prices pertain mostly to injectable
10 drugs that are not subject to FUL prices at this
11 time. Therefore we do not need to consider the new
12 AWP prices while we were compiling the new FUL list. If
13 you have any more questions please feel free to
14 e-mail me."
15 Does this refresh your recollection at
16 all about any conversations that arose within HCFA
17 or elsewhere about the fact that there were no FUL
18 prices on injectable drugs?
19 MS. MARTINEZ: Objection, form.
20 A. I could be wrong. And here again, this
21 isn't my e-mail. But what was the period of time
22 when that MFCU thing occurred?

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1 Q. I believe around 2000.
2 A. This inquiry might have come about
3 because of the MFCU issue and they were probably
4 asking this question because of that.
5 Q. And the MFCUs would have new -- they were
6 having First Databank publish new AWP prices for certain
7 drugs? Is that your recollection?
8 A. Right.
9 MS. MARTINEZ: Objection, form.
10 Q. Which might impact the FULs that you were
11 setting at HCFA?
12 A. I think that's what they were asking.
13 Q. And Ms. Pelter was saying that is not
14 going to be an issue because these new AWP prices
15 pertain mostly to injectable drugs, correct?
16 A. That's what she's saying.
17 Q. Do you recall any other discussion about
18 this issue?
19 A. There may have been. I don't remember
20 any further discussion.
21 (Exhibit Abbott 466 was
22 marked for

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1 identification.)
2 BY MR. TORBORG:
3 Q. For the record, what I've marked as
4 Abbott Exhibit 466 bears the Bates numbers HHD
5 006-0103 through 108. And I can represent to you,
6 Ms. Gaston, that this was a document that was pulled
7 from the OIG working paper files for their work on
8 the DOJ AWP effort, the report we looked at earlier.
9 I would ask you just to look at the first
10 page and just let me know if you've seen this. I
11 doubt you have.
12 A. (Reading.) And what was this pertaining
13 to again?
14 Q. This was a document that we found in the
15 working paper files for the OIG report concerning
16 the DOJ AWP effort?
17 MS. MARTINEZ: Objection, form.
18 A. Is this the MFCU?
19 Q. Yes.
20 A. Okay. I changed that term on you.
21 Q. That's fine. And my understanding,
22 deposing the individual who sent forth this

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1 document, this contains some comments that states
2 had made to OIG concerning those NAMFCU AWP.
3 MS. MARTINEZ: Objection, form. Or
4 objection to your comment. Let me ask you, this
5 hasn't been marked as an exhibit before, then, in
6 another deposition?
7 MR. TORBORG: I think it may have been.
8 If it has, I don't have that.
9 BY MR. TORBORG:
10 Q. In any event, I want to ask you about a
11 comment that's contained in the first page, the
12 third one down, the state NC. I'm assuming it's
13 North Carolina. The second line says "At a meeting
14 about the new prices, asked Larry Reed why not put
15 these prices on a FUL. HCFA responded that they
16 couldn't do that." Do you see that?
17 A. Yes.
18 Q. Do you recall attending any meetings
19 concerning the NAMFCU AWP's?
20 MR. WINGET-HERNANDEZ: Objection, form.
21 Q. In particular between the states and
22 HCFA.

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<p style="text-align: right;">Page 282</p> <p>1 MR. WINGET-HERNANDEZ: I have to object, 2 Counsel, to your manner of taking. You are using 3 this document to imply that it is notes of a meeting 4 that occurred at which this witness might have 5 attended when you know full well exactly where this 6 document came from, who produced it and the fact 7 that this witness would not have had anything to do 8 with it. It's improper for you to use the document 9 in this way. 10 MR. TORBORG: How do you know that she 11 wasn't at the meeting? 12 MR. WINGET-HERNANDEZ: You've already 13 received sworn testimony about how this information 14 was obtained from David Tawes, from the Office of 15 the Investigator General with which she has 16 absolutely no connection. 17 MR. TORBORG: Well, we established that 18 she was at the exit conference for this report. So 19 clearly she has a connection. 20 MR. WINGET-HERNANDEZ: And you 21 established in sworn testimony that this information 22 was the result of a telephone survey that was</p>	<p style="text-align: right;">Page 284</p> <p>1 discussion at that time. 2 Q. We'll do one more document quickly. This 3 will be Abbott Exhibit 467. 4 (Exhibit Abbott 467 was 5 marked for 6 identification.) 7 BY MR. TORBORG: 8 Q. For the record, what I've marked as 9 Abbott Exhibit 467 is a interrogatory response that 10 was provided by the United States in response to an 11 interrogatory issued by Abbott Laboratories. And I 12 ask you to take a look at that and let me know if 13 you are familiar with this document. 14 A. Yes, I am. 15 Q. Have you reviewed this before today? 16 A. Yes. 17 Q. Now, this document has been signed or 18 what we call in legal terminology verified by 19 someone named William Lasowski? 20 A. Yes. 21 Q. Do you know who that is? 22 A. He worked with Dennis Smith.</p>
<p style="text-align: right;">Page 283</p> <p>1 conducted by Mr. Tawes in which he was on the line 2 with a state person from North Carolina. 3 MR. TORBORG: That doesn't mean that was 4 the only meeting that discussed this issue. It's 5 clear this document suggests otherwise. 6 MR. WINGET-HERNANDEZ: I'm not objecting 7 to your question in the abstract. I'm objecting to 8 the manner in which you've used this document in 9 this instance. I think it's outrageous. 10 MR. TORBORG: Okay. 11 BY MR. TORBORG: 12 Q. Do you recall attending any meetings with 13 states concerning the NAMFCU AWP's? 14 A. I don't remember attending a meeting with 15 states on the NAMFCU. 16 Q. Do you recall any discussion of HCFA 17 stating that they could not put injectable drugs or 18 other drugs on the NAMFCU list on a FUL? 19 MS. MARTINEZ: Objection to form. 20 Q. Do you recall that being an issue of 21 discussion at any time? 22 A. No. I don't remember that being a</p>	<p style="text-align: right;">Page 285</p> <p>1 Q. How long has he been with HCFA? Do you 2 know? 3 A. I have no idea. 4 Q. Has he been there since you started? 5 A. I'm not sure. 6 Q. Do you know what his involvement has been 7 with the federal upper limit program? 8 A. I would say no involvement. Unless it 9 was prior to my time. 10 MR. TORBORG: We have one minute left on 11 the tape so why don't we go ahead and take a break 12 here and we'll adjourn at a time and place to be 13 decided later. Thank you for your time. 14 THE WITNESS: Okay. You're welcome. 15 THE VIDEOGRAPHER: This deposition 16 adjourns at 5:01 and consists of five tapes. 17 (Whereupon, at 5:01 p.m. the statement of 18 counsel was concluded.) 19 * * * * * 20 21 22</p>

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SIGNATURE OF WITNESS

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SUE GASTON

Subscribed and sworn to and before me
this _____ day of _____, 20____.

Notary Public

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